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Complete List of Authors:	Liu, Hui-ming; Shenzhen Kangning Hospital, Department of Public Health Chen, Guanjie; Shenzhen Kangning Hospital, Department of Public Health Li, Jinghua; Sun Yat-Sen University School of Public Health, Sun Yat-sen Global Health Institute Hao, Chun; Sun Yat-Sen University School of Public Health, Sun Yat-sen Global Health Institute Zhang, Bin; Shenzhen Kangning Hospital, Department of Public Health Bai, Yuanhan; Shenzhen Kangning Hospital, Department of Bipolar Disorders Song, Liangchen; Shenzhen Kangning Hospital, Department of Public Health Chen, Chang; Shenzhen Kangning Hospital, Department of Public Health Xie, Haiyan; Shenzhen Kangning Hospital, Department of Public Health Liu, Tiebang; Shenzhen Kangning Hospital, Department of Public Health Caine, Eric; University of Rochester Medical Center, Department of Psychiatry Hou, Fengsu; Shenzhen Kangning Hospital, Department of Public Health; Sun Yat-Sen University School of Public Health, Sun Yat-sen Global Health Institute
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An implementation study of suicide risk management among discharged psychiatric patients based on brief contact interventions and a sequential multiple assignment randomized trial: a study protocol

Huiming Liu[1, *], Guanjie Chen[1, *], Jinghua Li[2], Chun Hao[2], Bin Zhang[1], Yuanhan Bai[3], Liangchen Song[1], Chang Chen[1], Haiyan Xie[1], Tiebang Liu[1], Eric D. Caine[4], Fengsu Hou[1, 2, #]

1. Department of Public Health, Shenzhen Kangning Hospital/Shenzhen Mental Health Center

Address: No.1080 Cuizhu Road, Luohu District, Shenzhen Guangdong, China, 518020

2. Sun Yat-sen Global Health Institute, School of Public Health, Sun Yat-sen University

Address: No. 74 Zhongshan 2nd Road, Guangzhou, Guangdong China, 510080.

3. Department of Bipolar Disorders, Shenzhen Kangning Hospital/Shenzhen Mental Health Center (Pingshan Campus)

Address: No.77 Zhenbi Road, Pingshan District, Shenzhen Guangdong, China, 518118

4.Department of Psychiatry, University of Rochester Medical Center

Address: 601 Elmwood Ave, Box PSYCH, Rochester, NY, USA 14642

* Co-first authors

Correspondent author

Email Address:

Huiming Liu: huimingcsu@163.com

Guanjie Chen: chen_guan_jie@hotmail.com

Jinghua Li: lijinghua3@mail.sysu.edu.cn

Chun Hao: haochun@mail.sysu.edu.cn

Bin Zhang: johnbean_604@aliyun.com

Yuanhan Bai: baiyuanhan@163.com

Liangchen Song: SLC136823221043@126.com

Chang Chen: 807810612@qq.com

Haiyan Xie: 251309219@qq.com

Tiebang Liu: liutbsz@126.com

Eric D. Caine: eric_caine@urmc.rochester.edu

Fengsu Hou: houfengsu@gmail.com

Corresponding author and trial sponsor

Fengsu Hou, Address: Shenzhen Kangning Hospital/Shenzhen Mental Health Center, No.1080 Cuizhu Road, Luohu District, Shenzhen Guangdong, China, 518020. Telephone number: +86-0755-25533524. Email: houfengsu@gmail.com

Word account: 5099

Abstract:

Introduction

The post-discharge suicide risk among psychiatric patients is significantly higher than it among patients with other diseases and general population. The brief contact interventions (BCIs) are recommended to decrease the risk in areas with limited mental health service resource like China. This study aims to develop a post-discharge suicide intervention strategy based on BCIs and explore its implementability based on the Implementation Outcome Framework.

Methods and analysis

This study will invite psychiatric patients and family members, clinical and community mental health service providers as the community team to develop a post-discharge suicide intervention strategy. The study will recruit 312 patients with psychotic symptoms and 312 patients with major depressive disorder discharged from Shenzhen Kangning Hospital (SKH) in a Sequential Multiple Assignment Randomized Trial (SMART). Participants will be randomized into two intervention groups to receive BCIs at different frequencies, and the re-randomization will be applied at 3 months after discharge. Follow-ups are scheduled at 1, 3, 6 and 12 months after discharge. With the Intent-to-treat (ITT) approach, generalized estimating equation and survival analysis will be applied. This study will also collect qualitative and quantitative information on implementation and service outcomes from the community team.

Ethics/dissemination

This study has received ethical approval from the Ethics Committee Review Board of SKH. All participants will provide written informed consent prior to enrollment. The findings of the study will be disseminated through peer-reviewed scientific journals, conference presentations, and a report will be submitted to the National Natural Science Foundation of China as the concluding report of this funded project, and to the mental health authorities in the Shenzhen to refine and apply evidence-based and pragmatic interventions into health systems for post-discharge suicide prevention.

Trial registration number: NCT04907669

Keywords Psychiatric patients, Post-discharge suicide, Brief contact interventions, Sequential multiple assignment randomized trial, Implementation science

Strengths and limitations

1. This is the protocol study that evaluate the implementation of an evidence-based intervention (brief contact interventions, BCIs) for post-discharge suicide risk among psychiatric patients in China.

2. A well-designed sequential multiple assignment randomized trial (SMART) is embedded in the study to investigate the effectiveness of the BCIs reducing post-discharge suicide risk among patients with psychotic symptoms and patients with major depression disorders.

3. The application of community-based participatory research approach will

provide an opportunity to investigate patients and mental health service providers' attitude towards the quality, safety, value, and sustainability of the post-discharge suicide intervention strategy.

4. Despite the sample size of SMART is well calculated and powered on previous studies, it is modest.

Introduction

Suicide is an acknowledged global public health concern. In China, the annual average suicide rate decreased from 23 per 100,000 people between 1995 and 1999 to 6.75 per 100,000 people between 2012 and 2015, and reversed trends were observed in some certain groups; in comparison, the rate was 10.5 per 100,000 people globally in 2016 reported by the World Health Organization (WHO)[1-4]. The Chinese national data from 2017 reported rates of 4.31 and 7.66 per 100,000 for urban and rural residents, respectively, with suicide is the fifth leading cause of death[5].

Patients discharged from psychiatric settings carry substantially greater risk for suicide. The pooled rate of suicide among discharged psychiatric patients was 484 per 100,000 person-years within 12 months worldwide, and it was 2950, 2060 and 1132 per 100,000 person-years within 1 week, 1 month and 3 months, respectively[6-15]. We know of only one study involving persons of Chinese ethnicity, which found a rate of 1062 per 100,000 persons during the year following discharge in Hong Kong, where community mental health services (influence by programs in the UK and in Australia) have been funded far more generously and, thus, been more resourceful in services than those in mainland China[8].

For patients with severe mental disorders in China, which include schizophrenia, schizoaffective disorder, paranoid psychosis, bipolar disorder, psychotic disorders due to epilepsy, or intellectual developmental disorder with psychotic disorders, they will receive follow-ups from community mental health workers after discharge according to the Code of Practice for the Management and Treatment of Severe

Mental Disorders (2018 Edition) that requires psychiatric facilities to report all patients with severe mental disorders in the Information Management System for Severe Mental Disorders[16]. However, the follow-ups focus on the risk of violent behaviors towards the public rather than post-discharge suicide.

For patients with other mental disorders, reports and follow-ups are not required. Psychiatrist may occasionally report individual patients with non-severe mental disorders who are at risk for suicide to the information system as appropriate, and once reported, community mental health workers must conduct follow-ups in accordance with the Code and focus on suicide risk and related mental disorder symptoms. Other patients with suicide risk who that are not reported rely on initiative visit to out-patient clinics or contracting with psychological crisis workers for post-discharge suicide interventions.

As an evidence-based strategy, brief contact interventions (BCIs) are recommended to decrease post-discharge suicide risk in areas of limited mental health resources[12 17-19]. BCIs are a series of non-intrusive interventions at low cost aiming to develop long term contact with discharged psychiatric patients by phone calls, caring letters, postcards, text messages, emergency green cards and crisis cards, etc. [19-22]. The key is to send messages to discharged patients (as well as their spouses and family members, relatives, friends, and colleagues) at a predetermined frequency expressing greetings, encouragement, caring and support, and reminding them of psychological crisis assistance and mental health services. The proposed hypothesis of BCIs decreasing the post-discharge suicide risk is to increase patients' social

connectedness and social support after discharge[23-26].

The World Health Organization (WHO) reported BCIs could decrease the post-discharge suicide risk among psychiatric patients effectively (OR=0.20, 95%CI: 0.09~0.42), and recommended to build BCIs in the suicide intervention framework[12]. In a randomized controlled trial (RCT) study, Motto et al reported the incidence of post-discharge suicide among intervention group was 8.48% (33/389) comparing with 14.10% (64/454) in control group[27]; however, in the followed 15-year cohort study, the significance of differences in post-discharge suicide incidence between groups wore off after five years[23]. Similar RCT studies reported BCIs could decrease suicide ideation, the number of suicide attempts, the risk of self-harm and suicide death[17 28-32]. In China, studies usually applied BCIs integrated with health education, consulting, assertive community treatment, and case management into comprehensive suicide intervention strategies, and reported effectiveness in reducing repeated attempted suicide, violent behaviors, and compliance to medication[33-39]. However, few studies reported inconsistencies about the effectiveness of BCIs reducing post-discharge suicide ideation, attempts and deaths, which can be explained by different frequencies (weekly, bi-weekly, monthly, or quarterly), types of BCIs (calls, caring cards, emails, or letters) and major outcomes (improvement of psychiatric symptoms, compliance to medication, and post-discharge suicide)[37 40-44].

In summary, most studies implemented BCIs monthly. Though few of them increased the frequency during the first week to first month after discharge, the frequency was reduced to monthly or bi-monthly which could be insufficient to

maintain the effect on post-discharge suicide intervention. Meanwhile, BCIs aim to decrease post-discharge suicide by increasing social connectedness and social support, but current studies did not measure the improvement of the two mediators during intervention or other confounding factors. Further, studies only evaluated the effectiveness and did not evaluate the feasibility and sustainability in daily work.

Hence, our specific aims include: 1) to develop an intervention strategy against post-discharge suicide for Chinese psychiatric patients based on BCIs; 2) to determine the best frequency of BCIs based on Sequential Multiple Assignment Randomized Trial; 3) to evaluate the effectiveness of the intervention strategy and explore its implementability based on the Implementation Outcome Framework (IOF).

Methods and analysis

This protocol has been written in accordance with the SPIRIT (Standard Protocol Items for Randomized Trials) statement[45].

In this study, we will adopt the definition of suicide behaviors in behavioral continuum proposed by Professor Shuiyuan Xiao in the Chinese cultural context (Table 1)[46]. We define suicide risk as the probability of an individual's death by suicide over a given time interval reflected by the intensity and frequency of suicidal ideation, suicidal plan, suicidal preparation, and attempted suicide.

Prior study

We conducted a prior study in Shenzhen Kangning Hospital (SKH) in early 2019.

During January 1st to March 31st, there were 1,349 discharged patients who aged 18 years and above, diagnosed with mental disorders, with ID, residence, and source of income, and had been hospitalized for 3 days at least, and 689 of them were diagnosed with suicide risk at admission. Of 689 patients, 515 of them completed follow-up survey. In the three-month follow-up, there were 20 attempted suicide and five completed suicide deaths after discharge, and the rate was 3883.5 (20/515) and 970.9 (5/515) per 100,000 people, respectively.

Implementation science framework

Evidence-based interventions and practices are poorly implemented, and it could take up to 17 years to adopt and integrate the interventions and practices into routine work by practitioners and policymakers[47-49]. To close the know-do gap and accelerate the implementation, implementation science aims to develop systematic methods and strategies to identify and address key points that promote or impede the process[50 51]. We adopt the Implementation Outcomes Framework (IOF) that evaluates implementation strategies by implementation outcomes, service outcomes and client outcomes, including acceptability, sustainability, fidelity, efficiency, effectiveness, satisfaction, and function et al (Figure 1)[52 53]. Based on IOF, we identify this study as a type-1 hybrid design implementation study that determines effectiveness and explores the context of routine implementation[54].

Table 1 The definition of suicide behaviors in this study

Suicide behaviors	Definition
Suicidal ideation	Having a clear intent to harm oneself without a clear plan, nor taking any preparation or actions.
Suicidal plan	Having a clear plan to harm oneself without taking any preparation or actions.
Suicidal preparation	Taking any preparation to commit suicide without taking actions to harm oneself.
Attempted suicide	Taking actions to commit suicide with a certain intensity of wish to die, which did not directly result in a fatal outcome.
Completed suicide	Taking actions to commit suicide with a certain wish to die and directly resulting in death

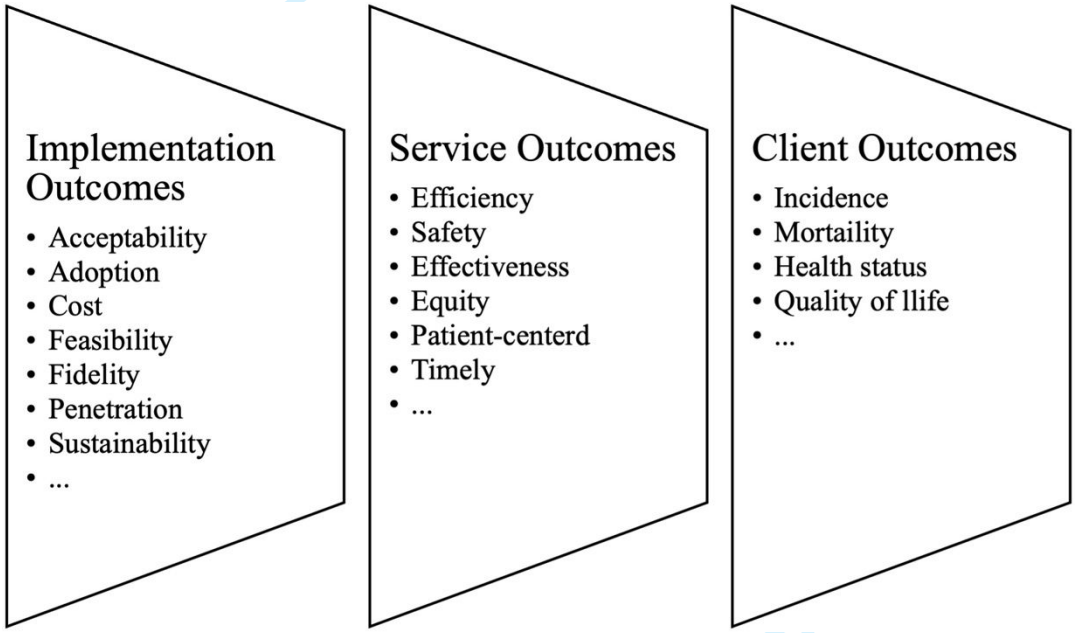

Figure 1 The Implementation Outcomes Framework

Study setting

This study will be implemented in SKH, the only public psychiatric hospital in Shenzhen with over 1500 inpatient beds, 11,590 person-time of inpatients, and 369,000 person-time outpatient visits per year. Shenzhen is with a population of 13.03 million residents, in which 8.48 million are internal migrants of varied

sociodemographic features cross China[55]. The reported life-time prevalence of any mental disorders (excluding dementia) in Shenzhen was 21.87%, and the life-time prevalence of any mood disorders and any anxiety disorders was 9.62% and 14.45%[56]. In comparison, the life-time prevalence of any mental disorders (excluding dementia), any mood disorders and any anxiety disorders was 16.60%, 7.40% and 7.60% in China, respectively[57].

Study design

This is a mixed-methods study with two stages (Figure 2). The first stage is to develop the intervention strategy by individual in-depth and focus groups interviews; and the second stage is to implement the strategy and evaluate the implementation quantitatively by a randomized trial and qualitatively by focus group interviews.

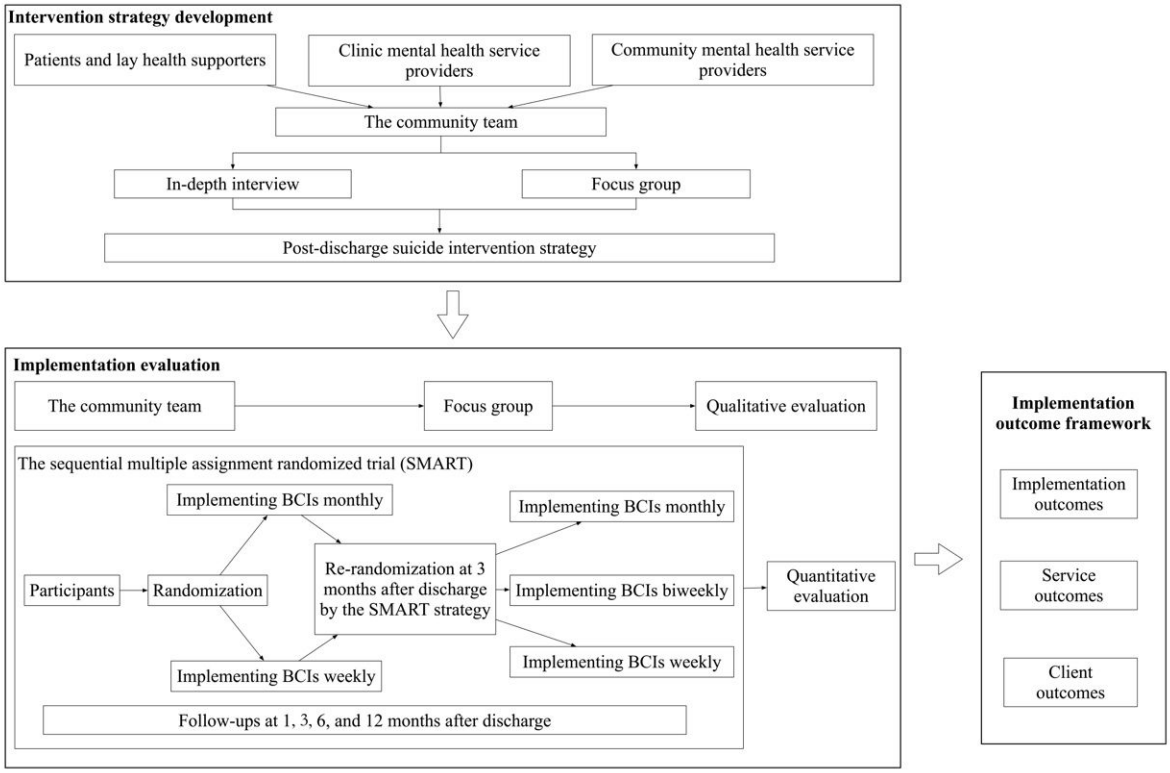

Figure 2 The Framework of the Study Design

The community-based participatory research

We aim to recruit discharged psychiatric patients and their lay health care supporters (LHSs) who are usually their family members, psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers as the community team that will provide a Chinese context under the community-based participatory research (CBPR) framework[58-60]. In specific, the framework would help this study:

- explore the feasibility of implementing BCIs against suicide risk after discharge,
- understand the needs for suicide risk management after discharge from related health care service providers and acceptors,
- integrate suicide risk management experiences from the community,
- discuss, develop, and revise the intervention strategy with the community.

We categorize the community team into three sub-groups, the patients-LHSs group, the clinic mental health service provider group (psychiatrists and nurses, and psycho-crisis intervention team members), and the community mental health service provider group (community mental health workers and mental health social workers).

Intervention development

We will conduct three focus group interviews in each sub-group and ten to fifteen cases of individual in-depth interview with the community to avoid bias in focus groups and to protect privacy related to personal experience in suicide and suicide

intervention. The themes include: 1) key points in suicide risk management after discharge, 2) how to develop BCIs content and delivery BCIs appropriately and feasibly to increase social connectedness and social support, 3) how to improve compliance to treatment and increase subsequent visits after discharge. There will be scheduled meetings with the community to discuss and revise the intervention strategy before implementation.

Implementation evaluation

Based on IOF, we will conduct three focus group interviews in each sub-group to explore 1) patients' and LHSs' attitudes, acceptability, and understanding of the strategy, 2) the clinic and community mental health service providers' willingness, and feasibility to implement the strategy, 3) the effectiveness, efficiency, equity, safety and timeliness of the strategy and whether it is patient-centered.

The qualitative study sample

Purposive sampling will be applied to recruit participants for the community team. For each type of sub-group, there will be five to eight members. The inclusion criteria for the clinic and community mental health service provider groups are: 1) being 18 years and above, 2) having practiced in mental health service at least for 12 months, 3) providing written consent. The inclusion criteria for the patients-LHSs group will be illustrated later.

The sequential multiple assignment randomized trial

We will conduct the sequential multiple assignment randomized trial (SMART) to determine the best frequency to implement BCIs and investigate the patient outcomes in IOF. The SMART design reflects the idea of adaptive treatment strategies and dynamic treatment regimens that provide a sequence of decisions about the points at which to offer different interventions and a set of intervention options for each decision point [61-63]. There will be two stages of treatment (Figure 3).

Stage 1: After recruitment and baseline survey, participants will be randomized into Group 1 and Group 2 where BCIs will be implemented monthly and weekly, respectively. Because suicide risk is the highest in the first three months among discharged psychiatric patients, we set the check point at three months after discharge to assess participants' suicide risk in both groups.

Stage 2: At the check point, for participants in Group 1, if the suicide risk increased, they will be re-randomized into Group 1a and Group 1b where BCIs will be implemented weekly and bi-weekly, respectively; if the suicide risk decreased or did not change, they will remain receiving BCIs monthly as Group 1c. For participants in Group 2, if the suicide risk increased or did not change, they will remain receiving BCIs weekly as Group 2a; if the suicide risk decreased, they will be re-randomized into Group 2b and Group 2c where BCIs will be implemented monthly and bi-weekly, respectively.

After the re-randomization, participants will continue to receive BCIs till 12 months after discharge, and the suicide risk will be evaluated at 1, 3, 6 and 12 months

after discharge.

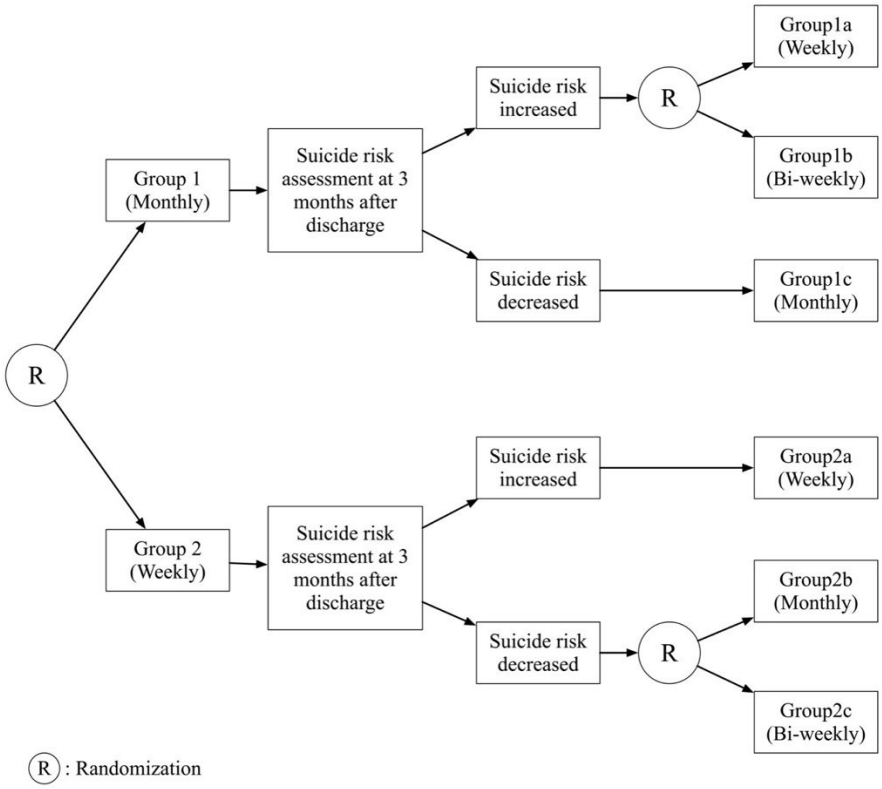

Figure 3 The SMART design of this study

The quantitative study sample

We plan to implement the strategy in patients with psychotic symptoms and patients with major depressive disorder (MDD), as in representative of severe and non-severe mental disorders, separately.

The inclusion criteria for patients are: 1) being 18 years and above, 2) being diagnosed with psychotic symptoms or MDD, 3) having received inpatient care for three days or more, 4) living in Shenzhen and having no plan to leave Shenzhen in the following 12 months after discharge, and 5) being able to read text messages, answer phone calls on mobile phones or use WeChat on smart phones. WeChat is the most widely used app in China with about 11 billion active users in the first

quarter of 2020[64]. Considering participants' suicide risk, we will also recruit their lay health care supporters (LHSs) to receive BCIs at the same frequency. The inclusion criteria are: 1) being 18 years and above, 2) without diagnosis of any mental disorder, 3) being the main lay health care supporter in the family, 4) living in Shenzhen and having no plan to leave Shenzhen in the following 12 months after discharge, and 5) being able to read text messages, answer phone calls on mobile phones or use WeChat on smart phones.

Patients who refuse to provide written consent and who are with cognitive impairment that prevents providing informed consent due to either dementia or current psychosis episodes, and who are with no ID, stable residence nor any source of income will be excluded. Particularly, patients discharged by families' or patients' demand ignoring medical advice will be excluded.

Sample size

The sample size was calculated to estimate the primary effect in SMART trial[65]. We set the rate of type I error α at 0.05, the rate of type II error β at 0.20, the power (1-β) at 0.80, the moderate effect size d at 0.35[66], and the sample size is 130 for Group 1 and Group 2, 260 in total; considering dropout, we will increase the sample size by 20%, and the final sample size is 312 participants. We will conduct two SMART trials in patients with psychotic symptoms and MDD separately, and the sample size for each trial is 312 (624 patients in total).

Randomization and mask

After recruitment and the baseline survey, we will assign participants into Group 1 and Group 2 by simple randomization in R program[67]. At the check point in the SMART trial, we will re-assign participants into Group 1a, Group 1b, Group 1c, Group 2a, Group 2b, and Group 2c based on their suicide risk by simple randomization in R program. The allocation ratio in randomization will be 1:1. Participants, LHSs, nurses who perform recruitment and baseline survey, and investigators who perform follow-ups will be blinded to the assignment.

Brief contact intervention

The BCI in this study is a series of structured messages, and it will primarily implement on the WeChat platform due to its popularity in China. Messages will be delivered to participants by pushing feeds through WeChat. If participants did not use smartphones, messages will be delivered by mobile text messages or by phone calls. Though the final details are yet to be determined by the CBPR study, we expect to structure messages into six components including introduction, greetings for previous complains, mental health promotion, encouragement, and coping strategies, remind of treatment and subsequent visit, and crisis intervention resource.

Noted, the same messages will also be sent to patients' LHSs to remind patients through their families for subsequent visits and upcoming follow-up surveys, and to remind LHSs that patients are at risk of post-discharge suicide and need attention and care, and the necessities of seeking crisis intervention in a timely manner.

Data collection

To evaluate post-discharge suicide risk more cautiously and to provide crisis intervention in time, we will conduct face-to-face interview to collect information. Trained nurses in SKH will recruit participants and perform baseline survey. As mentioned, we encourage subsequent visits to SKH out-patient clinics in BCIs, and research assistants will contact participants, schedule visits, and complete follow-up questionnaires after out-patient visits at 1, 3, 6 and 12 months after discharge. If participants refused subsequent visits, we would schedule home visits to complete the survey by research assistants and community mental health workers. Dropout is defined as 1) participants or their LHSs request to quit the study and stop receiving any brief contact messages, 2) participants or their LHSs refuse follow-up surveys either at out-patient clinics or at home, 3) participants pass away by accidents or other health problems except suicide.

Study outcomes and measurements

The study outcomes are based on the Implementation Outcomes Framework.

Implementation outcomes

Acceptability and *adoption* will be evaluated by the community's attitudes generating from qualitative interviews. And *the adoption rate* will be measured by the number of participants who subscribe to follow the study's WeChat Platform divided by the number of participants who remain as followers at the end of the study.

Feasibility will be evaluated by mental health service providers' attitudes generating from qualitative interviews.

Cost will be measured by the total cost on implementing the SMART trial, which will be recorded to assess the economic benefits of the intervention during the study.

Fidelity will be measured by staged checklist for adherence to study protocol, the quality, and the competence of the study.

Service outcomes

Efficiency will be measured by the number of daily brief contacts delivered to participants through WeChat, text messages and phone calls during implementation. *Safety* (whether there would be any potential harm/danger to patients) will be evaluated by the community's attitudes generating from qualitative interviews.

Effectiveness will be measured by the comparison of the trajectories of suicide ideation and suicidality from baseline to 3 and 12 months after discharge, respectively.

Equity be evaluated by the community in focus group interviews that how the intervention strategy considers and address the disparities in social groups.

Patient-centeredness be evaluated by the community in focus group interviews that how well the intervention strategy considers and meets the needs and demands of patients, and whether the study fully consider participants' feelings.

Timeliness will be measured by the time that the research team cost to respond to participants' feedbacks and requests for crisis intervention.

Client outcomes

The trajectories of suicide risk (suicide ideation and suicidality) at 1-, 3-. 6- and 12-month post-discharge are the primary outcome of this study. The trajectories of social connectedness and social support are the secondary outcomes.

Suicide ideation will be measured by the Beck Suicide Ideation Scale-Chinese Version (BSI-CV), which has been translated and modified in the Chinese context, and it has been validated and widely applied in China[68-73]. The BSI-CV includes 19 items evaluating specific attitudes, ideations, behavior and plans to commit suicide during the past week, and each item scores from 0 to 2 with a total score ranging from 0 to 38, and a higher score indicates higher risk of suicide.

Suicidality will be measured by the suicidality module of the Mini-International Neuropsychiatric Interview (M.I.N.I.-Suicidality), which has been validated in China, to assess suicide risk for in- and out- patients, we will also evaluate participants' suicidality by this scale[74-76]. In the 6-item scale, dichotomous items ("No" or "Yes") evaluate wish to be dead, self-hurt, suicide ideation, plan, current and ever attempts during the past month, and "yes" to each item is assigned to score 1, 2, 6, 10, 10 and 4, respectively, with a higher total score indicating higher level of suicide risk.

Social connectedness will be measured by the Social Connectedness Scale (SCS) to evaluate participants' social connected ness after discharge, which has been validated in China[77 78]. The SCS is a 20-item scale, and each item is on a 6-Likert continuum (from "Strongly disagree" to "Strongly agree") scoring from 1 to 6[78]. A higher total score indicates a higher level of social connectedness.

Social support will be measured by the 23-item Duke Social Support Index (DSSI) to evaluate participants' social support after discharge [79]. The Chinese version of DSSI have been validated and applied in China[80-83]. The DSSI investigates social support by social interaction, perceived social support and instrumental social support. Every answer has been assigned a score, and the total reflects the sum of the items ranging from 11 to 45. A higher total score indicates a higher level of social support.

Covariates

We will develop a questionnaire to collect information of covariates, and the questionnaire will be validated in pilot.

Demographic information will be collected at baseline by self-made questionnaire including age, marital status, occupation, income, Hukou (household residence registration), and residence time in Shenzhen.

Times of re-hospitalization for mental disorders will be measured by responses to the question "How many times have you been hospitalized for mental disorders?" in follow-ups.

The usage of crisis intervention will be measured by the responses to the question "How many times have you called the research team or the Crisis Intervention Hotline for help after discharged from hospital?" in follow-ups.

Perceived stigma will be evaluated the Chinese version of Link Perceived Devaluation-Discrimination Scale [84 85]. The scale contains 12 items assessing the

extent to which a person believes that other people will devalue or discriminate against someone with a mental illness. Each item is on a 4-Likert continuum (from "Strongly disagree" to "Strongly agree") scoring from 1 to 4. A higher total score indicates a higher level of perceived stigma.

Self-efficacy will be evaluated by the Chinese version of the General Self-Efficacy Scale[86]. The scale contains 10 items, and each item is on a 4-Likert continuum (from "Not at all true" to "Exactly true") scoring from 1 to 4. A higher total score indicates a higher level of self-efficacy. The total score's trajectory from baseline to three months after discharge will be recorded and compared.

Compliance to treatment will be evaluated by a 4-item self-administered questionnaire. The questionnaire inquires whether the patients take medications under the instruction on prescriptions. Each item is on a 4-Likert continuum (from "Not following the instruction" to "Exactly following the instruction") scoring from 1 to 4. A higher total score indicates a higher level of compliance to treatment.

Statistical analyses

We will perform the intention-to-treat (ITT) approach in analyses of the originally assigned groups. Demographic and baseline information between participants in Group 1 and Group 2, as well as between participants with psychotic symptoms and MDD, will be presented in the form of mean (standard deviation, SD), the 95% confidence intervals (CIs) for continuous variables, and percentages for categorical variables. ITT analysis will be performed on the final data collected at 12 months

after discharge.

We will use independent t-test (for continuous variables) and Chi-square test (categorical variables) to compare the differences between groups. For repeated measured outcomes, we will use Generalized Estimating Equation (GEE) to explore the time-trends and adjust for potential confounding variables.

We will use survival analyses (SA) to compare the effect of BCIs reducing post-discharge suicide risk at endpoint between participants in Group 1 and Group 2, as well as between patients with psychotic symptoms and MDD. The model will take mediating factors into account. We will run pairwise comparisons between re-assigned groups by GEE ([Group1a+Group1c] vs. [Group1b+Group1c] vs. [Group2a+Group2b] vs. [Group2a+Group2c]). And we will use path analysis to explore to validate the hypothesis that BCIs could decrease post-discharge suicide risk by increasing social connectedness and social support. Further, we plan to use Average Cost-Effectiveness Ratio (ACER) to assess the economic benefits, and the ACER reflects the incremental cost of reducing one unit of post-discharge suicide risk.

Multiple imputation will be used to account for the missing values assuming they are missing at random. We set statistical significance at 0.05 and all analyses will be two-sided. All data analyses will be performed using the R program[67].

Qualitative analyses

We will analyze qualitative data with a three-step procedure[87 88].

Open coding Four coders independently will code the qualitative data into categorical and numerical codes, and share their codes. If the codes were different over the same response, there would be a discussion until reaching consensus.

Axial coding During analysis, the authors will associate codes to each other, and re-conceptualized categories and sub-categories to fully elaborate codes.

Selective coding The authors will compare different categories of codes and examined the associations to identify a core category that could represent the key themes to research questions and related to other categories. The selective coding is at a higher level compared with axial coding, and the core category could be a new category created during analysis.

Lastly, we will enter the categorical and numerical data into a database for analysis and generated the final theories.

Data monitoring and quality assurance

The study will receive overall supervision from the Department of Research and Education Management in SKH, who will quarterly monitor the progress and review the quality and completeness of data. All data will be stored at encrypted password-protected severs owned by SKH, and only the research team members have the access. Nurses who will recruit participants and complete baseline survey and research assistants will be responsible for identifying and recruiting participants, obtaining informed consent, and double data entry. A formal data monitoring committee will not be considered for the conduct of this study as this is a low-risk

intervention; however, the study will be annually reviewed by the Ethics Committee Review Board in SKH.

Ethics and dissemination

The study protocol (10th May2021, version 1.1) has received approval from the Ethics Committee Review Board of SKH, and any violations of the study protocol will be recorded and reported to the board.

The findings of the study will be disseminated through peer-reviewed scientific journals, conference presentations, and a report will be submitted to the National Natural Science Foundation of China as the concluding report, and to the mental health authorities in the Shenzhen Municipal Health Commission to refine and apply evidence-based and pragmatic interventions into health systems for post-discharge suicide prevention.

Patient and public partnership

In this study, we will apply the CBPR principles which allow patients, family members and the public (psychiatric doctors, nurses, mental health social workers and community mental health doctors) to participate in developing and evaluating the intervention strategy against post-discharge suicide.

Discussion

To our knowledge, this study is the first implementation study in China to include a sizable number of in-hospitalized patients with psychotic symptoms and MDD in

a community-based participatory setting and a continuum of mental health care aiming to decrease post-discharge suicide risk. The target population is patients discharged from psychiatric settings. We have discussed possible recruitment strategies, the involvement of LHSs and community mental health workers, and the priority of post-discharge suicide risk management in out prior study in SKH, which will lead to the successful implementation of the current study. We believe the results may provide implementational evidence for policymakers in Shenzhen on reducing suicide risk for patients discharged from psychiatric settings in resource-limited settings.

Interventions that decrease post-discharge suicide risk among psychiatric patients include BCIs, psychological therapies (i.e., behavior therapy, cognitive therapy, and behavior cognitive therapy), medication treatment and integrated interventions (i.e., case management and assertive community treatment)[18 89 90]. Though interventions like case management and assertive community treatment (ACT) are effective to prevent post-discharge death, they are more viable and practical in countries/regions with adequate mental health and social resource, and it is not suitable for widespread implementation in resource limited countries/regions, like China where there are about 2.20 psychiatric professionals per 100,000 persons including psychiatrists and community mental health workers[91 92]. Though it is slightly higher in Shenzhen (2.50 psychiatric professionals per 100,000 persons), Shenzhen is limited with mental health resource comparing with Canada (14.68), the U.S. (10.54) and Japan (11.87) [91 93]. As we have stated, with limited mental health recourse, the focus of China's

current management policy over discharged psychiatric patients is to decrease the risk of violent behaviors towards the public. Hence, it is crucial to explore implementation effectiveness of low-cost interventions like BCIs in China.

Short length of stay, side effects of medication treatments, low treatment adherence, history of suicide attempts, and hospitalization and discharge experiences were associated with increased suicide risk among patients discharged from psychiatric settings[94]. Meanwhile, studies also report the loneliness, feelings of lost and uncertainty lead to post-discharge suicide: a) patients are aware of suicide risk, but they don't know how to manage it and don't know how and who to ask for help; b) without doctor's or nurse's orders/advice, patients may lose daily goals and do not know what to do after discharge; c) patients may actively avoid contact with others, and would feel lonely even if others take the initiative to care; d) patients may fell self-balm and self-guilt due to the illness or suicide attempts; e) patients may experience frustrations in recovery which lead to reconsiderations of suicide[23-25]. These studies not only provide a context that explain the high suicide risk within 12 months, especial the first three months, among patients discharged from psychiatric setting, but also indicate the importance of social connectedness and social support that BCIs could deliver to decrease post-discharge risk.

This study has several strengths. First, it addresses the continuum of mental health care from clinic to post-discharge settings and emphasizes on social connectedness and social support. Second, the study focuses on implementation outcomes. We will not only focus on the decrease of post-discharge suicide risk, but also the

acceptability, adoption, fidelity, efficiency, safety, equity, and patient-centeredness, etc. Third, the study will apply the CBPR framework to develop a culturally tailored and locally contextual intervention strategy, which will fully consider benefits of all stakeholders (patients and family members, clinic, and community mental health service providers) in post-discharge suicide risk management. Fourth, we will apply the SMART design to explore the effect of BCIs on decreasing post-discharge suicide risk and to determine the best frequency to deliver BCIs. The SMART design could improve validity by allowing simultaneous evaluation of the results of different interventions or combinations of interventions, reduce dropouts by reassigning participants who are not sensitive to the initial intervention or do not have the desired outcome to another intervention, examine what intervention participants have received and when, and promise all participants receive interventions[61-63].

Although this study may hold promise for better implementation, service and client outcomes, there are potential limitations. Though we will have a sample size with the power to detect outcomes, we will only recruit patients with psychotic symptoms and MDD who cannot be the represent all patients discharged from psychiatric settings, while the setting of the study is in Shenzhen that may not represent the entire China, thus the generalizability of our findings will be limited.

Trial Registration and status

This study has been registered in the ClinicalTrials.gov registry on May 31, 2021 (NCT04907669). The anticipated recruitment date for the CBPR study will be September 1, 2021, and the anticipated recruitment date for the SMART trial will be

January 1, 2022.

References

1. Phillips MR, Li X, Zhang Y. Suicide rates in China, 1995–99. *The Lancet* 2002;359(9309):835-40. doi: 10.1016/s0140-6736(02)07954-0
2. Liu Z, Huang Y, Ma C, et al. Suicide rate trends in China from 2002 to 2015. *Chinese Mental Health Journal* 2017;31(10):756-67.
3. Jiang H, Niu L, Hahne J, et al. Changing of suicide rates in China, 2002–2015. *Journal of Affective Disorders* 2018;240:165-70. doi: 10.1016/j.jad.2018.07.043
4. World Health Organization. Global Health Observatory (GHO) data 2017. Available from: https://www.who.int/gho/mental_health/suicide_rates/en/ Accessed at June 28th 2020.
5. National Health Commission of the People's Republic of China. Yearbook of Health in the People's Republic of China. Beijing: Peking Union Medical College Press 2018.
6. Goldacre M, Seagroatt V, Hawton K. Suicide after discharge from psychiatric inpatient care. *The Lancet* 1993;342(8866):283-86. doi: 10.1016/0140-6736(93)91822-4
7. Geddes JR, Juszczak E. Period trends in rate of suicide in first 28 days after discharge from psychiatric hospital in Scotland, 1968-92. *BMJ* 1995;311(7001):357-60. doi: 10.1136/bmj.311.7001.357
8. Appleby L, Shaw J, Amos T, et al. Suicide within 12 months of contact with mental health services: national clinical survey. *BMJ* 1999;318(7193):1235-39. doi: 10.1136/bmj.318.7193.1235
9. Meehan J, Kapur N, Hunt IM, et al. Suicide in mental health in-patients and within 3 months of discharge. *British Journal of Psychiatry* 2006;188(2): 129-134.
10. Hunt IM, Kapur N, Webb R, et al. Suicide in recently discharged psychiatric patients: a case-control study. *Psychological Medicine* 2009;39(3):443-49.
11. Bickley H, Hunt IM, Windfuhr K, et al. Suicide within two weeks of discharge from psychiatric inpatient care: a case-control study. *Psychiatric Services* 2013;64(7):653-59. doi: 10.1176/appi.ps.201200026
12. World Health Organization, Preventing suicide: A global imperative. 2014: World Health Organization. Available from https://www.who.int/mental_health/suicide-prevention/world_report_2014/en/. Assessed at September 19th 2019.
13. Chung DT, Ryan CJ, Hadzi-Pavlovic D, et al. Suicide rates after discharge from psychiatric facilities: a systematic review and meta-analysis. *JAMA Psychiatry* 2017;74(7):694. doi: 10.1001/jamapsychiatry.2017.1044
14. Haglund A, Lysell H, Larsson H, et al. Suicide immediately after discharge from psychiatric inpatient care: a cohort study of nearly 2.9 million discharges.

Journal of Clinical Psychiatry 2019;80(2) doi: 10.4088/JCP.18m12172

15. Chung D, Hadzi-Pavlovic D, Wang M, et al. Meta-analysis of suicide rates in the first week and the first month after psychiatric hospitalisation. *BMJ Open* 2019;9(3):e023883. doi: 10.1136/bmjopen-2018-023883
16. National health commission of People's Republic of China.the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 Edition): National health commission of People's Republic of China 2018. Available from http://www.nhc.gov.cn/jkj/s7932/201806/90d5fe3b7f48453db9b9beb85dfdc8a8.shtml. Accessed at September 23rd 2019.
17. Fleischmann A, Bertolote JM, Wasserman D, et al. Effectiveness of brief intervention and contact for suicide attempters: a randomized controlled trial in five countries. *Bulletin of the World Health Organization* 2008;86:703-09.
18. Zalsman G, Hawton K, Wasserman D, et al. Suicide prevention strategies revisited: 10-year systematic review. *The Lancet Psychiatry* 2016;3(7):646-59. doi: https://doi.org/10.1016/S2215-0366(16)30030-X
19. Riblet NBV, Shiner B, Young-Xu Y, et al. Strategies to prevent death by suicide: Meta-analysis of randomised controlled trials. *British Journal of Psychiatry* 2017;210(6):396-402. doi: 10.1192/bjp.bp.116.18779
20. Luxton DD, June JD, Comtois KA. Can postdischarge follow-up contacts prevent suicide and suicidal behavior? *Crisis* 2013;34(1):32-41.
21. Falcone G, Nardella A, Lamis DA, et al. Taking care of suicidal patients with new technologies and reaching-out means in the post-discharge period. *World Journal of Psychiatry* 2017;7(3):163-76. doi: 10.5498/wjp.v7.i3.163
22. Messiah A, Notredame CE, Demarty AL, et al. Combining green cards, telephone calls and postcards into an intervention algorithm to reduce suicide reattempt (AlgoS): P-hoc analyses of an inconclusive randomized controlled trial. *PloS One* 2019;14(2):e0210778.
23. Motto JA, Bostrom AG. A Randomized Controlled Trial of Postcrisis Suicide Prevention. *Psychiatric Services* 2001;52(6):828-33. doi: 10.1176/appi.ps.52.6.828
24. Cutcliffe JR, Links PS, Harder HG, et al. Understanding the risks of recent discharge: the phenomenological lived experiences – "Existential Angst at the Prospect of Discharge". *Crisis* 2012;33(1):21-29. doi: 10.1027/0227-5910/a000096
25. Riblet N, Shiner B, Scott R, et al. Exploring psychiatric inpatients' beliefs about the role of post-discharge follow-up care in suicide prevention. *Military Medicine* 2019;184(1-2):e91-e100.
26. Hare-Duke L, Dening T, de Oliveira D, et al. Conceptual framework for social connectedness in mental disorders: systematic review and narrative synthesis. *Journal of Affective Disorders* 2019;245:188-99. doi: https://doi.org/10.1016/j.jad.2018.10.359
27. Motto JA. Suicide prevention for high-risk persons who refuse treatment. *Suicide and Life-Threatening Behavior* 1976;6(4):223-30.

28. Carter GL, Clover K, Whyte IM, et al. Postcards from the EDge project: randomised controlled trial of an intervention using postcards to reduce repetition of hospital treated deliberate self poisoning. *BMJ* 2005;331(7520):805. doi: 10.1136/bmj.38579.455266.E0
29. Carter GL, Clover K, Whyte IM, et al. Postcards from the EDge: 24-month outcomes of a randomised controlled trial for hospital-treated self-poisoning. *British Journal of Psychiatry* 2007;191(6):548-53. doi: 10.1192/bjp.bp.107.038406
30. Cebrià AI, Parra I, Pàmias M, et al. Effectiveness of a telephone management programme for patients discharged from an emergency department after a suicide attempt: controlled study in a Spanish population. *Journal of affective disorders* 2013;147(1-3):269-76.
31. Hassanian-Moghaddam H, Sarjami S, Kolahi A-A, et al. Postcards in Persia: a twelve to twenty-four month follow-up of a randomized controlled trial for hospital-treated deliberate self-poisoning. *Archives of Suicide Research* 2017;21(1):138-54. doi: 10.1080/13811118.2015.1004473
32. Comtois KA, Kerbrat AH, DeCou CR, et al. Effect of Augmenting standard care for military personnel with brief caring text messages for suicide prevention: a randomized clinical trial. *JAMA Psychiatry* 2019;76(5):474-83. doi: 10.1001/jamapsychiatry.2018.4530
33. Zhang S, Zhou G. Intervention of violent and suicidal behaviour of mental patients in the community. *Journal of Clinical Psychological Medicine* 1999;9(2):77-78.
34. Fu Y, Shen J,Dang W, et al. Effects of psychological intervention on the young people of attempted suicide. *Chinese Mental Health Journal* 2007;21(8):571-74.
35. Bi B. Intervention for emergency department patients who attempt suicide in ShenYang general hospital: an 1-year follow-up study. China Medical University, 2010.
36. Xu D, Zhang X, Li X, et al. Effectiveness of 18-month psychosocial intervention for suicide attempters. *Chinese Mental Health Journal* 2012;26(1):24-29.
37. Chen W-J, Ho C-K, Shyu S-S, et al. Employing crisis postcards with case management in Kaohsiung, Taiwan: 6-month outcomes of a randomised controlled trial for suicide attempters. *BMC Psychiatry* 2013;13(1):191.
38. Zhao W, Peng M, Zhao Y, et al. The mechanism of assertive community treatment effects on the suicidality in schizophrenia patients. *Chinese Journal of Clinical Psychology* 2018;26(3):620-23.
39. Yuan Q, Qian M, Tao L. The effect of individualized information support on suicidal attitude in patients with depressive disorder. *Chinese Primary Health Care* 2019;33(2):45-48.
40. Cotgrove A, Zirinsky L, Black D, et al. Secondary prevention of attempted suicide in adolescence. *Journal of Adolescence* 1995;18(5):569-77.
41. Evans J, Evans M, Morgan HG, et al. Crisis card following self-harm: 12-month follow-up of a randomised controlled trial. *British Journal of Psychiatry*

2005;187(2):186-87.
42. Vaiva G, Walter M, Al Arab AS, et al. ALGOS: the development of a randomized controlled trial testing a case management algorithm designed to reduce suicide risk among suicide attempters. *BMC Psychiatry* 2011;11(1):1. doi: 10.1186/1471-244X-11-1
43. Reger MA, Luxton DD, Tucker RP, et al. Implementation methods for the caring contacts suicide prevention intervention. *Professional Psychology: Research and Practice* 2017;48(5):369-77. doi: 10.1037/pro0000134
44. Yuan Y, Wang G, Shen L, et al. The effect of suicide risk for implementing hospital-community-family integrated care in depression patients. *Chinese Nursing Research* 2016;30(11):4174-76.
45. Tetzlaff, J.M., Moher, D. & Chan, AW. Developing a guideline for clinical trial protocol content: Delphi consensus survey. *Trials* 2012;l13:176. https://doi.org/10.1186/1745-6215-13-176
46. Xiao S, Zhou L, Xu H. Suicide prevention and crisis intervention -the concept and certification of suicide. *Journal of Clinical Psychiatry* 2005;15(5):298-99.
47. Balas EA, Boren SA. Managing clinical knowledge for health care improvement. *Yearbook of Medical Informatics* 2000;9(01):65-70.
48. Grant J, Green L, Mason B. Basic research and health: a reassessment of the scientific basis for the support of biomedical science. *Research Evaluation* 2003;12(3):217-24.
49. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *Journal of the Royal Society of Medicine* 2011;104(12):510-20.
50. Eccles MP, Mittman BS. Welcome to Implementation Science. *Implementation Science* 2006;1(1):1. doi: 10.1186/1748-5908-1-1
51. Bauer MS, Damschroder L, Hagedorn H, et al. An introduction to implementation science for the non-specialist. *BMC Psychology* 2015;3(1):32-32. doi: 10.1186/s40359-015-0089-9
52. Proctor EK, Landsverk J, Aarons G, et al. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Administration and Policy in Mental Health and Mental Health Services Research* 2009;36(1):24-34.
53. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* 2011;38(2):65-76.
54. Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care* 2012;50(3):217-26. doi: 10.1097/MLR.0b013e3182408812
55. Statistics Bureau of Shenzhen Municipality. Shenzhen Statistical Yearbook 2019. Beijing: China Satatistics Press Co. 2019.

56. Hu J, Hu C, Duan W, et al. Survey on mental disorders among registered residents and non-registered residents in Shenzhen. *Chinese Journal of Epidemiology* 2009;30(6):543-48.
57. Huang Y, Wang Y, Wang H, et al. Prevalence of mental disorders in China: a cross-sectional epidemiological study. *The Lancet Psychiatry* 2019;6(3):211-24. doi: 10.1016/S2215-0366(18)30511-X
58. Israel BA, Schulz AJ, Parker EA, et al. Review of community-based research: assessing partnership approaches to improve public health. *Annual Review of Public Health* 1998;19(1):173-202.
59. Israel BA, Schulz AJ, Parker EA, et al. Community-based participatory research: policy recommendations for promoting a partnership approach in health research. *Education for Health* 2001;14(2):182-97.
60. Smikowski J, Dewane S, Johnson ME, et al. Community-based participatory research for improved mental health. *Ethics & Behavior* 2009;19(6):461-78.
61. Murphy SA. An experimental design for the development of adaptive treatment strategies. *Statistics in Medicine* 2005;24(10):1455-81.
62. Lei H, Nahum-Shani I, Lynch K, et al. A "SMART" design for building individualized treatment sequences. *Annual Review of Clinical Psychology* 2012;8:21-48.
63. Wallace MP, Moodie EE, Stephens DA. SMART thinking: a review of recent developments in sequential multiple assignment randomized trials. *Current Epidemiology Reports* 2016;3(3):225-32.
64. Tencent Holdings Ltd. The 2020 First Quarter Results 2020. Available from: https://cdc-tencent-com-1258344706.image.myqcloud.com/uploads/2020/05/18/fc1afc176e4604f3a05602a467b259ad.pdf. Accessed at July 28th 2020.
65. Crivello A, Levy J, Murphy S. Statistical methodology for a smart design in the development of adaptive treatment strategies: University Park, PA: The Pennsylvania State University, The Methodology Center, 2007.
66. Cohen J. Statistical power analysis for the behavioural sciences. Hillsdale, NJ: Laurence Erlbaum Associates: Inc, 1988.
67. R: A language and environment for statistical computing [program], 2013.
68. Li X, Phillips MR, Zhang Y, et al. Reliability and validity of the Chinese version of Beck Scate for Suicide Ideation (BSI-CV) among university students. *Chinese Mental Health Journal* 2011;25(11):862-66
69. He H, Yang Y. Path analysis on the influencing factors of suicide ideation among college students in Beijing. *Chinese Journal of School Health* 2015;36(1):80-83.
70. Ai M, Chen JM, Wang MJ, et al. The impulsiveness and aggression among suicide attempters in college students. *Chinese Journal of Nervous and Mental Diseases* 2011;37(11):650-55
71. Zhou ZJ, Yang xi, Liu TB, et al. Influencing factors to suicide behaviors among adolescent students of four schools in Shenzhen. *Chinese Journal of School Health* 2015;36(9):1330-33.

72. Beck AT, Steer RA, Ranieri WF. Scale for suicide ideation: psychometric properties of a self-report version. *Journal of Clinical Psychology* 1988;44(4):499-505. doi: 10.1002/1097-4679(198807)44:4<499::aid-jclp2270440404>3.0.co;2-6

73. Li X, Phillips MR, Tong YS, et al. Reliability and validity of the Chinese version of Beck Suicide Ideation Scale (BSI-CV) in adult community residents. *Chinese Mental Health Journal* 2010;24(4):250-55.

74. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *The Journal of Clinical Psychiatry* 1998;58(Suppl 20):22–33.

75. Si T, Shu L, Dang W, et al. Evaluation of the Reliability and Validity of Chinese Version of the Mini.International Neuropsychiatric Interview in Patients with Mental Disorders. *Chinese Mental Health Journal* 2009;23(7):493-97,503.

76. Lecrubier Y, Sheehan DV, Weiller E, et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to the CIDI. *European Psychiatry* 1997;12(5):224-31.

77. Fan X, Wei J, Zhang J. On Reliability and validity of Social Connectedness Scale-Revised in Chinese middle school students. *Journal of Southwest China Normal University (Natural Science Edition)* 2015;40(8):118-22.

78. Lee RM, Robbins SB. Measuring belongingness: the social connectedness and the social assurance scales. *Journal of Counseling Psychology* 1995;42(2):232.

79. Koenig HG, Westlund RE, George LK, et al. Abbreviating the Duke Social Support Index for use in chronically ill elderly individuals. *Psychosomatics* 1993;34(1):61-9. doi: 10.1016/s0033-3182(93)71928-3

80. Zhou M, Qiu J, Mou Y, et al. Reliability and validity of the 23-Duke Social Support Scale among rural elderly population. *Chinese Journal of Public Health* 2015;31(11):1369-72.

81. Hou F, Cerulli C, Wittink M, et al. Depression, social support and associated factors among women living in rural China: a cross-sectional study. *BMC Women's health* 2015;15(1):28.

82. Zhang J, Conwell Y, Wieczorek WF, et al. Studying Chinese suicide with proxy-based data: reliability and validity of the methodology and instruments in China. *Journal of Nervous and Mental Disease* 2003;191(7):450.

83. Jia C, Zhang J. Psychometric characteristics of the Duke Social Support Index in a young rural Chinese population. *Death Studies* 2012;36(9):858-69.

84. Link BG, Struening EL, Neese-todd S, et al. On describing and seeking to change the experience of stigma. *Psychiatric Rehabilitation Skills* 2002;6(2):201-31. doi: 10.1080/10973430208408433

85. Xu H. A study of stigma of people with Schizophrenia and relationship with medication compliance. Peking Union Medical College, 2008.

86. Zhang JX, Schwarzer R. Measuring optimistic self-beliefs: A Chinese adaptation

of the General Self-Efficacy Scale. *Psychologia: An International Journal of Psychology in the Orient* 1995;38(3):174–181.
87. Liamputtong P. Researching the vulnerable: A guide to sensitive research methods: Sage 2006.
88. Liamputtong P. Qualittive Research Methods. Fourth ed. Australia: Oxford University Press 2013:218-237.
89. Inagaki M, Kawashima Y, Kawanishi C, et al. Interventions to prevent repeat suicidal behavior in patients admitted to an emergency department for a suicide attempt: a meta-analysis. *Journal of Affective Disorder*s 2015;175:66-78.
90. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies: a systematic review. *JAMA* 2005;294(16):2064-74.
91. World Health Organization. Global Health Observatory data repository 2019. Available from http://apps.who.int/gho/data/?theme=main. Assessed at October 23rd 2019.
92. Zhao W, Zhu Y, Luo XW, et al. The assertive community treatment model for severe mental disorders: A review. Chinese Mental Health Journal 2014;28(2):89-96.
93. Shenzhen Mental Health Center. Shenzhen Mental Health Work Information Brief Shenzhen: Shenzhen Mental Health Center, 2020.
94. Schechter M, Goldblatt MJ, Ronningstam E, et al. Postdischarge suicide: a psychodynamic understanding of subjective experience and its importance in suicide prevention. *Bulletin of the Menninger Clinic* 2016;80(1):80-96.

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Contributors All authors contributed to the conceptualization and the design of this study. FH obtained the funding and contributed to the theoretical framework of the study. FH and HL conceived the prototype of the intervention, the study design, and the creation of the team. HL and GC drafted the initial manuscript together. JL and CH provided the sampling, randomization, and analytical strategy. BZ and YB conceived the content of the intervention and provided crisis intervention service in the study. LS, CC and HX contributed to the implementation of the study. TL and

EDC steered the direction of the study and contributed significantly to the revision of the manuscript. All authors read and revised the initial manuscript and approved the final version.

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Competing interests All authors declare no competing interest.

Ethics approval Ethics Committee Review Board of Shenzhen Kangning Hospital (2021-K006-01-1).

Data sharing statement We will make quantitative data publicly available through FigShare 12 months after the main studies are published in peer-reviewed journals. The data will contain deidentified demographic information, primary and secondary outcomes, and other covariate outcomes. Please contact the PI to request for the use of the data, and the requests should include detail contact information of applicants, the purpose of study, and the analysis plan.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_4 , 29 , clinicaltrials.gov _____
	2b	All items from the World Health Organization Trial Registration Data Set	__Not applicable_____
Protocol version	3	Date and version identifier	__26_____
Funding	4	Sources and types of financial, material, and other support	__37_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1, 2, 36_____
	5b	Name and contact information for the trial sponsor	_2_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_36_____

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_25_____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_6-9_____
	6b	Explanation for choice of comparators	__15,16_____
Objectives	7	Specific objectives or hypotheses	_9_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_12-16,18_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_11,12_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_14,16,17_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_15,_18_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_15_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_19___ _____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	__Not applicable_

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_19-23_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_15,16_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_13,17_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_19_____

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_18_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_18_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_18_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_18_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_Not applicable_____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_19_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_19_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_19,25_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_23,24_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_23,24_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_25_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_Not applicable_
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_Not applicable_
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_Not applicabl _
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__26_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_Not applicable_
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_25_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_Not applicable_
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_37_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_37_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_25,37_____ _
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_Not applicable__
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_26_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_Not applicable__
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_37____ ____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Not applicable__

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_Not applicable__

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

BMJ Open

A sequential multiple assignment randomized trial of a brief contact intervention for suicide risk management among discharged psychiatric patients: an implementation study protocol

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A sequential multiple assignment randomized trial of a brief contact intervention for suicide risk management among discharged psychiatric patients: an implementation study protocol

Huiming Liu Ph.D.[1, *], Guanjie Chen M.D.[1, *], Jinghua Li Ph.D.[2], Chun Hao Ph.D.[2], Bin Zhang M.S.[1], Yuanhan Bai M.S.[3], Liangchen Song M.S.[1], Chang Chen M.S.[1], Haiyan Xie M.S.[1], Tiebang Liu M.D.[1], Eric D. Caine M.D.[4], Fengsu Hou Ph.D.[1, 2, #]

1. Department of Public Health, Shenzhen Kangning Hospital/Shenzhen Mental Health Center

Address: No.1080 Cuizhu Road, Luohu District, Shenzhen Guangdong, China, 518020

2. Sun Yat-sen Global Health Institute, School of Public Health, Sun Yat-sen University

Address: No. 74 Zhongshan 2nd Road, Guangzhou, Guangdong China, 510080.

3. Department of Bipolar Disorders, Shenzhen Kangning Hospital/Shenzhen Mental Health Center (Pingshan Campus)

Address: No.77 Zhenbi Road, Pingshan District, Shenzhen Guangdong, China, 518118

4.Department of Psychiatry, University of Rochester Medical Center

Address: 601 Elmwood Ave, Box PSYCH, Rochester, NY, USA 14642

* Co-first authors

Correspondent author

Email Address:

Huiming Liu: huimingcsu@163.com

Guanjie Chen: chen_guan_jie@hotmail.com

Jinghua Li: lijinghua3@mail.sysu.edu.cn

Chun Hao: haochun@mail.sysu.edu.cn

Bin Zhang: johnbean_604@aliyun.com

Yuanhan Bai: baiyuanhan@163.com

Liangchen Song: SLC136823221043@126.com

Chang Chen: 807810612@qq.com

Haiyan Xie: 251309219@qq.com

Tiebang Liu: liutbsz@126.com

Eric D. Caine: eric_caine@urmc.rochester.edu

Fengsu Hou: houfengsu@gmail.com

Corresponding author and trial sponsor

Fengsu Hou, Address: Shenzhen Kangning Hospital/Shenzhen Mental Health Center, No.1080 Cuizhu Road, Luohu District, Shenzhen Guangdong, China, 518020. Telephone number: +86-0755-25533524. Email: houfengsu@gmail.com

Word account: 5433

Abstract:

Introduction

The post-discharge suicide risk among psychiatric patients is significantly higher than it is among patients with other diseases and general population. The brief contact interventions (BCIs) are recommended to decrease suicide risk in areas with limited mental health service resources like China. This study aims to develop a post-discharge suicide intervention strategy based on BCIs and explore its implementability under the Implementation Outcome Framework.

Methods and analysis

This study will invite psychiatric patients and family members, clinical and community mental health service providers as the community team to develop a post-discharge suicide intervention strategy. The study will recruit 312 patients with psychotic symptoms and 312 patients with major depressive disorder discharged from Shenzhen Kangning Hospital in a Sequential Multiple Assignment Randomized Trial. Participants will be initially randomized into two intervention groups to receive BCIs monthly and weekly, and they will be re-randomized into three intervention groups to receive BCIs monthly, bi-weekly and weekly at 3 months after discharge according to the change of their suicide risk. Follow-ups are scheduled at 1, 3, 6 and 12 months after discharge. With the Intent-to-treat approach, generalized estimating equation and survival analysis will be applied. This study will also collect qualitative and quantitative information on implementation and service outcomes from the

community team.

Ethics/dissemination

This study has received ethical approval from the Ethics Committee Review Board of SKH. All participants will provide written informed consent prior to enrollment. The findings of the study will be disseminated through peer-reviewed scientific journals, conference presentations. A project report will be submitted to the National Natural Science Foundation of China as the concluding report of this funded project, and to the mental health authorities in the Shenzhen to refine and apply evidence-based and pragmatic interventions into health systems for post-discharge suicide prevention.

Trial registration number: NCT04907669

Keywords Psychiatric patients, Post-discharge suicide, Brief contact interventions, Sequential multiple assignment randomized trial, Implementation science

Strengths and limitations

1. This is the protocol study that evaluates the implementation of an evidence-based suicide intervention strategy that reduces post-discharge suicide risk by brief contacts among psychiatric patients in China.

2. A well-designed sequential multiple assignment randomized trial (SMART) is

embedded to investigate the effectiveness of the BCIs reducing post-discharge suicide risk among patients with psychotic symptoms and patients with major depression disorders.

3. The application of community-based participatory research approach will provide an opportunity to investigate patients' and mental health service providers' attitude towards the quality, safety, value, and sustainability of the post-discharge suicide intervention strategy.

4. Despite the sample size of SMART is well calculated and powered by previous studies, it is modest.

Introduction

Suicide is an acknowledged global public health concern. In China, the annual average suicide rate decreased from 23 per 100,000 people between 1995 and 1999 to 6.75 per 100,000 people between 2012 and 2015[1-3]. In 2017, as the fifth leading cause of death, the reported suicide rate in China was 4.31 and 7.66 per 100,000 people in urban and rural, respectively[4]. In comparison, the World Health Organization (WHO) reported the global rate was 10.5 per 100,000 people in 2016[5].

Patients discharged from psychiatric settings carry substantially greater risk for suicide. The pooled rate of suicide among discharged psychiatric patients was 484 per 100,000 person-years within 12 months worldwide, and it was 2950, 2060 and 1132 per 100,000 person-years within 1 week, 1 month and 3 months, respectively[6-15]. We know of only one study involving persons of Chinese ethnicity, which found a rate of 1062 per 100,000 people during the year following discharge in Hong Kong, where community mental health services (influence by programs in the UK and in Australia) have been funded far more generously and, thus, been more resourceful in services than those in mainland China[8].

There is no specific mental health policy in China with respect to psychiatric patients at risk of post-discharge suicide. For patients with severe mental disorders in China, which include schizophrenia, schizoaffective disorder, paranoid psychosis, bipolar disorder, psychotic disorders due to epilepsy, or intellectual developmental disorder with psychotic disorders, they will receive follow-ups from community

mental health workers after discharge according to the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 Edition)[16]. In specific, the Code requires psychiatric facilities to report and register all patients with severe mental disorders in the Information Management System for Severe Mental Disorders, in which the patients will be rated from level 0 to 5 for the risk of violent behaviors. Registered patients will be rated as level 4 if conducted self-harm or attempted suicide, and the Code requires psychiatrists, family doctors, community mental health workers, mental health social workers, and the police to conduct joint follow-ups at least once every two weeks for patients at level 3 to 5. However, the follow-ups focus on the risk of violent behaviors towards the public rather than post-discharge suicide.

For patients with other mental disorders, registrations in the system and joint follow-ups are not required. Psychiatrists may occasionally report individual patients with non-severe mental disorders who are at risk for suicide to the information system as appropriate, and once reported, community mental health workers must conduct follow-ups in accordance with the Code focusing on suicide risk and related mental disorder symptoms. Other patients with suicide risk who are not reported will rely on active visit to out-patient clinics or contracting psychological crisis workers for post-discharge suicide interventions.

Brief contact interventions (BCIs) are evidence-based and have been recommended to decrease post-discharge suicide risk in areas of limited mental

health resources[12 17-19]. BCIs are a series of non-intrusive interventions at low cost aiming to develop long term contact with discharged psychiatric patients by phone calls, caring letters, postcards, text messages, emergency green cards and crisis cards, etc. [19-22]. The key is to send messages to discharged patients (as well as their spouses and family members, relatives, friends, and colleagues) at a predetermined frequency expressing greetings, encouragement, caring and support, and reminding them of psychological crisis assistance and mental health services. The proposed hypothesis of BCIs decreasing the post-discharge suicide risk is to increase patients' social connectedness and social support after discharge[23-26].

The WHO reported BCIs could decrease the post-discharge suicide risk among psychiatric patients effectively (OR=0.20, 95%CI: 0.09~0.42), and recommended integrating BCIs in the suicide intervention framework[12]. In a randomized controlled trial (RCT) study, Motto et al. reported the incidence of post-discharge suicide among intervention group was 8.48% (33/389) comparing with 14.10% (64/454) in control group[27]; however, in the followed 15-year cohort study, the significance of differences in post-discharge suicide incidence between groups wore off after five years[23]. Similar RCT studies reported BCIs could decrease suicide ideation, the number of suicide attempts, the risk of self-harm and suicide death[17 28-32]. In China, studies usually applied BCIs as one component of comprehensive suicide intervention strategies, in which health education, consulting, assertive community treatment, and case management were also included, and reported effectiveness in

reducing repeated attempted suicide, violent behaviors, and improving compliance to treatments[33-39]. However, few studies reported inconsistencies about the effectiveness of BCIs reducing post-discharge suicide ideation, attempts and deaths, which can be explained by different delivering frequencies (weekly, bi-weekly, monthly, or quarterly), types of BCIs (calls, caring cards, emails, or letters) and major outcomes (improvement of psychiatric symptoms, compliance to medication, or post-discharge suicide)[37 40-44].

In summary, most studies implemented BCIs monthly. Though few of them increased the delivering frequency from the first week to the first month after discharge, the frequency was reduced to monthly or bi-monthly, which could consequently be insufficient to maintain the effect on reducing post-discharge suicide risk in a long term. Meanwhile, most of the content and the implementation strategy were predetermined by researchers rather than patients' needs and expectations. BCIs aim to reduce post-discharge suicide by increasing social connectedness and social support, but current studies did not measure the improvement of the two mediators or other confounding factors including socioeconomic factors, stigma, physical health, and the use of mental health service, etc. Further, studies only evaluated the effectiveness and did not evaluate the feasibility and sustainability in daily work.

Hence, our specific aims include: 1) to develop an intervention strategy against post-discharge suicide risk for Chinese psychiatric patients based on BCIs; 2) to

determine the best delivering frequency of BCIs based on Sequential Multiple Assignment Randomized Trial; 3) to evaluate the effectiveness of the intervention strategy and explore its implementability under the Implementation Outcome Framework (IOF).

Methods and analysis

This protocol has been written in accordance with the SPIRIT (Standard Protocol Items for Randomized Trials) statement and COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist[45 46].

In this study, we will adopt the definition of suicide behaviors in a behavioral continuum proposed by Professor Shuiyuan Xiao in the Chinese cultural context (Table 1)[47]. We define suicide risk as the probability of an individual's death by suicide over a given time interval reflected by the intensity and frequency of suicide ideation, suicide plan, suicide preparation, and suicide attempts. Suicide risk will be evaluated by the Beck Suicide Ideation Scale-Chinese Version and the suicidality module of the Mini-International Neuropsychiatric Interview.

Insert Table 1 here.

Prior study

We conducted a prior study in Shenzhen Kangning Hospital (SKH) in early 2019. During January 1st to March 31st, there were 1,349 discharged patients who aged 18 years and above, diagnosed with mental disorders, with ID, residence, and source of

income, and had been hospitalized for 3 days at least, and 689 of them were diagnosed with suicide risk at admission. Of 689 patients, 515 of them completed the survey in a three-month follow-up. There were 20 attempted suicide cases and five completed suicide deaths, and the rate was 3883.5 (20/515) and 970.9 (5/515) per 100,000 people, respectively.

Implementation science framework

Evidence-based interventions and practices are poorly implemented, and it could take up to 17 years to adopt and integrate the interventions and practices into routine work by practitioners and policymakers[48-50]. To close the know-do gap and accelerate the implementation, implementation science aims to develop systematic methods and strategies to identify and address key points that promote or impede the process[51 52]. We adopt the Implementation Outcomes Framework (IOF) that evaluates implementation strategies by implementation outcomes, service outcomes and client outcomes, including acceptability, sustainability, fidelity, efficiency, effectiveness, satisfaction, and function et al. (Figure 1)[53 54]. Based on IOF, we identify this study as a type-1 hybrid design implementation study that determines effectiveness and explores the context of routine implementation[55].

Insert Figure 1 here.

Study setting

This study will be implemented in SKH, a public psychiatric hospital in Shenzhen

City with over 1500 in-patient beds, 11,590 person-time of in-patients, and 369,000 person-time out-patient visits in 2020. Despite there are general hospitals providing psychiatric out-patient services in Shenzhen, SKH is the only medical facility providing in-patient psychiatric services. Shenzhen is with a population of 13.03 million residents, in which 8.48 million are internal migrants of varied sociodemographic features cross China[56]. The reported life-time prevalence of any mental disorders (excluding dementia) in Shenzhen was 21.87%, and the life-time prevalence of any mood disorders and any anxiety disorders was 9.62% and 14.45%[57]. In comparison, the life-time prevalence of any mental disorders (excluding dementia), any mood disorders and any anxiety disorders was 16.60%, 7.40% and 7.60% in China, respectively[58].

Study design

This is a mixed-methods study with two stages (Figure 2). The first stage is to develop the intervention strategy by in-depth and focus group interviews; and the second stage is to implement the strategy and evaluate the implementation quantitatively by a randomized trial and qualitatively by focus group interviews. The anticipated start and end dates for the study are September 1st 2021 and June 30th 2023.

Insert Figure 2 here.

The community-based participatory research

We aim to recruit discharged psychiatric patients and their lay health care supporters (LHSs) who are usually family members, psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers as the community team that will provide a Chinese context under the community-based participatory research (CBPR) framework[59-61]. In specific, the framework would help this study:

- explore the feasibility of implementing BCIs against suicide risk after discharge,
- understand the needs for suicide risk management after discharge from related health care service providers and acceptors,
- integrate suicide risk management experiences from the community,
- discuss, develop, and revise the intervention strategy with the community.

We categorize the community team into three sub-groups, the patients-LHSs group and the clinic mental health service provider group (psychiatrists and nurses, and psycho-crisis intervention team members) which will be recruited from SKH, and the community mental health service provider group (community mental health workers and mental health social workers) which will be recruited from eight community health centers in Shenzhen.

Intervention development

We will conduct three focus group interviews with each sub-group. To avoid bias in focus group interviews and to protect privacy related to personal experience in suicide and suicide intervention, we will also conduct ten to fifteen cases of in-depth interview in total with members from each sub-group. The themes include: 1) key points in suicide risk management after discharge, 2) how to develop BCIs content and deliver BCIs appropriately and feasibly to increase social connectedness and social support, 3) how to improve compliance to treatment and increase subsequent visits after discharge. There will be scheduled meetings with the community to discuss and revise the intervention strategy before implementation.

Implementation evaluation

Based on IOF, we will conduct three focus group interviews in each sub-group to explore 1) patients' and LHSs' attitudes, acceptability, and understanding of the strategy, 2) the clinic and community mental health service providers' willingness, and feasibility to implement the strategy, 3) the effectiveness, efficiency, equity, safety and timeliness of the strategy and whether it is patient-centered.

The qualitative study sample

Purposive sampling will be applied to recruit participants face-to-face for the community team. For each sub-group, there will be five to eight members. The

inclusion criteria for the clinic and community mental health service provider groups are: 1) being 18 years and above, 2) having practiced in mental health service at least for 12 months. The inclusion criteria for the patients-LHSs group will be illustrated later. All participants will receive 100 Yuan (about $15.42) to offset their efforts and cost of taking part.

The qualitative data collection

All co-authors from SKH have qualitative research experience and will conduct focus group and in-depth interviews in privacy-protected meeting rooms of SKH. There will be an interviewer, a recorder of field note, and an observer for interviews. The interviewer will introduce the aims of the study, the purpose of the interview and obtain written informed consent including audio recording consent before interviews begin. The interview guide questions are showed in supplementary file (Supplement). Audio recordings and field notes will be transcribed into text for analysis.

The sequential multiple assignment randomized trial

We will conduct the sequential multiple assignment randomized trial (SMART) to determine the best frequency to implement BCIs and investigate the patient outcomes in IOF. The SMART design reflects the idea of adaptive treatment strategies and dynamic treatment regimens that provide a sequence of decisions about the points at which to offer different interventions and a set of intervention options for each decision point[62-64]. There will be two stages (Figure 3).

Stage 1: After recruitment and baseline survey, participants will be randomized into Group 1 and Group 2 where BCIs will be implemented monthly and weekly, respectively. Because suicide risk is the highest in the first three months among discharged psychiatric patients, we set the check point at three months after discharge to assess participants' suicide risk in both groups.

Stage 2: At the check point, for participants in Group 1, if the suicide risk increased, they will be re-randomized into Group 1a and Group 1b where BCIs will be implemented weekly and bi-weekly, respectively; if the suicide risk decreased or did not change, they will remain receiving BCIs monthly as Group 1c. For participants in Group 2, if the suicide risk increased or did not change, they will remain receiving BCIs weekly as Group 2a; if the suicide risk decreased, they will be re-randomized into Group 2b and Group 2c where BCIs will be implemented monthly and bi-weekly, respectively. After the re-randomization, participants will continue to receive BCIs until 12 months after discharge, and the suicide risk will be evaluated at 1, 3, 6 and 12 months after discharge.

Insert Figure 3 here.

The quantitative study sample

We plan to implement the strategy in patients with psychotic symptoms and patients with major depressive disorder (MDD), as in representative of severe and non-severe mental disorders.

The inclusion criteria for patients are: 1) being 18 years and above, 2) being diagnosed with psychotic symptoms or MDD, 3) having received inpatient care for three days or more, 4) living in Shenzhen and having no plan to leave Shenzhen in the following 12 months after discharge, and 5) being able to read text messages, answer phone calls on mobile phones, use WeChat or any application on smart phones. WeChat is the most widely used app in China with about 11 billion active users in the first quarter of 2020[65]. Considering participants' suicide risk, we will also recruit their LHSs to receive BCIs at the same frequency. The inclusion criteria are: 1) being 18 years and above, 2) without diagnosis of any mental disorder, 3) being the main lay health care supporter for the patient, 4) living in Shenzhen and having no plan to leave Shenzhen in the following 12 months after discharge, and 5) being able to read text messages, answer phone calls on mobile phones, use WeChat, or any application on smart phones. All participants will receive 100 Yuan (about $15.42) to offset their efforts and cost of taking part.

Patients who are with cognitive impairment that prevents providing written informed consent due to either dementia or current psychosis episodes and who are with no ID, stable residence nor any source of income will be excluded. Particularly, patients discharged on families' or patients' demand against medical advice will be excluded.

Sample size

The sample size was calculated to estimate the primary effect between Group 1 and Group 2 in the trial[66]. We set the rate of type I error α at 0.05, the rate of type II error β at 0.20, the power (1-β) at 0.80, the moderate effect size d at 0.35[67], and the sample size is 130 for each group, 260 in total; considering dropout, we will increase the sample size by 20%, and the final sample size is 312 participants. We will conduct two SMART trials in patients with psychotic symptoms and MDD separately, and the sample size for each trial is 312 (624 patients in total). We aim to recruit participants from January 1st 2022 until the sample size is reached.

Randomization and mask

After recruitment and the baseline survey, we will assign participants into Group 1 and Group 2 by block randomization in R program[68]. At the check point in the SMART trial, we will re-assign participants into Group 1a, Group 1b, Group 1c, Group 2a, Group 2b, and Group 2c based on their suicide risk by simple randomization in R program. The allocation ratio in randomization will be 1:1. The randomization will be performed by a statistician in the research team. Patients, LHSs, nurses who perform recruitment and baseline survey, the statistician who performs randomization, and investigators who perform follow-ups will be blinded to the assignment.

Brief contact intervention

The BCI in this study is a series of structured messages, and it will primarily be delivered through pushing feeds on WeChat due to its popularity in China, and an iOS/Android application will also be applied to deliver the intervention. If participants did not use smartphones, messages will be delivered by mobile text messages or by phone calls. Though the content of messages is yet to be determined by the CBPR study, we expect to structure messages into six components including introduction, greetings for previous complaints, mental health promotion, encouragement and coping strategies, remind of treatment and subsequent visit, and crisis intervention resource. Noted, the same messages will also be sent to LHSs. Figure 4 shows an example of the brief contact intervention delivered through WeChat.

Insert Figure 4 here.

Quantitative data collection

To evaluate post-discharge suicide risk more cautiously and to provide crisis intervention in time, we will conduct face-to-face interview to collect information. After research assistants introduce the study and obtain written informed consent, trained nurses in SKH will recruit participants and perform baseline survey before discharge. As mentioned, we encourage subsequent visits to SKH out-patient clinics in BCIs, and research assistants will contact participants to schedule out-patient visits

and complete follow-up surveys during the visits at 1, 3, 6 and 12 months after discharge. If participants refused follow-ups in out-patient settings, we would schedule home visits to complete the survey by research assistants and community mental health workers. If patients did not respond, research assistants will contact their LHSs to obtain participants' recent updates and help them schedule out-patient visits for patients if necessary. Dropout is defined as 1) participants or their LHSs request to quit the study and stop receiving any brief contact messages; 2) participants or their LHSs refuse follow-up surveys either at out-patient clinics or at home; 3) participants pass away by accidents or other health problems except suicide. Particularly, at each time point of follow-ups, we will contact patients and LHSs up to three times. If neither of them responded, they would be treated as dropout.

Study outcomes and measurements

The study outcomes are based on the Implementation Outcomes Framework.

Implementation outcomes

Acceptability and *adoption* will be evaluated by the community's attitudes generating from qualitative interviews. *The adoption rate* will be measured by the number of participants who subscribe to follow the study's WeChat Platform or the iOS/Android smartphone application divided by the number of participants who remain as followers at the end of the study.

Feasibility will be evaluated by mental health service providers' attitudes

generated from qualitative interviews.

Cost will be measured by the total cost of implementing the SMART trial, which will be recorded to assess the economic benefits of the intervention during the study.

Fidelity will be measured by a staged checklist for adherence to the study protocol, the quality, and the competence of the study.

Service outcomes

Efficiency will be measured by the number of daily brief contacts delivered to participants through WeChat, the application, text messages, and phone calls during implementation.

Safety that whether implementing BCIs would be any potential harm/danger to patients will be evaluated by the community's attitudes generated from qualitative interviews.

Effectiveness will be measured by the comparison of the trajectories of suicide ideation and suicidality from baseline to 3 and 12 months after discharge between Group 1 and Group 2, respectively.

Equity will be evaluated by the community in focus group interviews that how the intervention strategy considers and address the disparities in social groups.

Patient-centeredness be evaluated by the community in focus group interviews that how well the intervention strategy considers and meets the needs and demands of patients, and whether the strategy fully considers participants' feelings.

Timeliness will be measured by the time that the research team cost to respond to participants' feedbacks and requests for crisis intervention.

Client outcomes

The trajectories of suicide risk (suicide ideation and suicidality) from baseline to 3- and 12-month post-discharge are the primary outcomes; while the trajectories of suicide risk from 3-month to 12-month post-discharge are the secondary outcomes. The trajectories of social connectedness and social support from baseline to 3- and 12-month post-discharge are the secondary outcomes.

Suicide ideation will be measured by the Beck Suicide Ideation Scale-Chinese Version (BSI-CV), which has been translated and modified in the Chinese context, and it has been validated and widely applied in China[69-74]. The BSI-CV includes 19 items evaluating specific attitudes, ideations, behavior and plans to commit suicide during the past week, and each item scores from 0 to 2 with a total score ranging from 0 to 38, and a higher score indicates higher level of suicide risk.

Suicidality will be measured by the suicidality module of the Mini-International Neuropsychiatric Interview (M.I.N.I.-Suicidality), which has been validated in China, to assess suicide risk for in- and out- patients, we will also evaluate participants' suicidality by this scale[75-77]. In the 6-item scale, dichotomous items ("No" or "Yes") evaluate wish to be dead, self-hurt, suicide ideation, plan, current and ever attempts during the past month, and "yes" to each item is assigned to score 1, 2, 6, 10, 10 and

4, respectively, with a higher total score indicating higher level of suicide risk.

Social connectedness will be measured by the Social Connectedness Scale (SCS) to evaluate participants' social connected ness after discharge, which has been validated in China[78 79]. The SCS is a 20-item scale, and each item is on a 6-Likert continuum (from "Strongly disagree" to "Strongly agree") scoring from 1 to 6[79]. A higher total score indicates a higher level of social connectedness.

Social support will be measured by the 23-item Duke Social Support Index (DSSI) to evaluate participants' social support after discharge[80]. The Chinese version of DSSI has been validated and applied in China[81-84]. The DSSI investigates social support by social interaction, perceived social support, and instrumental social support. Every answer has been assigned a score, and the total reflects the sum of the items ranging from 11 to 45. A higher total score indicates a higher level of social support.

Covariates

We will develop a questionnaire to collect information about covariates, and the questionnaire will be validated in pilot.

Demographic information will be collected at baseline by self-made questionnaire including age, marital status, occupation, income, Hukou (household residence registration), and residence time in Shenzhen.

Times of re-hospitalization for mental disorders will be measured by responses to

the question "How many times have you been hospitalized for mental disorders?" in follow-ups.

The usage of crisis intervention will be measured by the responses to the question "How many times have you called the research team or the Crisis Intervention Hotline for help after discharged from hospital?" in follow-ups.

Perceived stigma will be evaluated by the Chinese version of Link Perceived Devaluation-Discrimination Scale [85 86]. The scale contains 12 items assessing the extent to which a person believes that other people will devalue or discriminate against someone with a mental illness. Each item is on a 4-Likert continuum (from "Strongly disagree" to "Strongly agree") scoring from 1 to 4. A higher total score indicates a higher level of perceived stigma. The trajectories of patients' perceived stigma from baseline to 3- and 12- month after discharge will be analyzed.

Self-efficacy will be evaluated by the Chinese version of the General Self-Efficacy Scale[87]. The scale contains 10 items, and each item is on a 4-Likert continuum (from "Not at all true" to "Exactly true") scoring from 1 to 4. A higher total score indicates a higher level of self-efficacy. The total score's trajectory from baseline to three months after discharge will be recorded and compared. The trajectories of patients' self-efficacy from baseline to 3- and 12- month after discharge will be analyzed.

Compliance to treatment will be evaluated by a 4-item self-administered questionnaire. The questionnaire inquires whether the patients take medications under the instruction on prescriptions. Each item is on a 4-Likert continuum (from

"Not following the instruction" to "Exactly following the instruction") scoring from 1 to 4. A higher total score indicates a higher level of compliance to treatment. The change of patients' compliance from baseline to 3- and 12- month after discharge will be analyzed.

Statistical analyses

We will perform the in analyses. Demographic and baseline information between participants in Group 1 and Group 2, as well as between participants with psychotic symptoms and MDD, will be presented in the form of mean (standard deviation, SD), the 95% confidence intervals (CIs) for continuous variables, and percentages for categorical variables.

We will use independent t-test (for continuous variables) and Chi-square test (categorical variables) to compare the differences between groups. For repeated measured outcomes, we will use Generalized Estimating Equation (GEE) to explore the time-trends and adjust for potential confounding variables.

We will use survival analyses (SA) to compare the effect of BCIs reducing post-discharge suicide risk at endpoint between participants in Group 1 and Group 2, as well as between patients with psychotic symptoms and MDD. The model will take mediating factors into account. We will run pair-wise comparisons between re-assigned groups by GEE ([Group1a+Group1c] vs. [Group1b+Group1c] vs. [Group2a+Group2b] vs. [Group2a+Group2c]). And we will use path analysis to

validate the hypothesis that BCIs could decrease post-discharge suicide risk by increasing social connectedness and social support. Further, we plan to use the Bootstrap percentile method to calculate the Average Cost-Effectiveness Ratio (ACER) that reflects the cost of reducing one unit of post-discharge suicide risk.

Multiple imputation will be used to account for the missing values, assuming they are missing at random. We set statistical significance at 0.05 and all analyses will be two-sided. All data analyses will be performed in the R program[67].

Qualitative analyses

We will code the qualitative data into the categorical and numerical data with a three-step procedure, and then apply content analysis method to analyze data in R program[88 89].

Open coding Four coders will independently code the qualitative data into categorical and numerical codes, and share their codes. If the codes were different over the same response, there would be a discussion until reaching consensus.

Axial coding During analysis, the authors will associate codes to each other, and re-conceptualized categories and sub-categories to fully elaborate codes.

Selective coding The authors will compare different categories of codes and examined the associations to identify a core category that could represent the key themes to research questions and related to other categories. The selective coding is at a higher level compared with axial coding, and the core category could be a new

category created during analysis.

Lastly, we will enter the categorical and numerical data into a database for content analysis and generated the final results.

Data monitoring and quality assurance

The study will receive overall supervision from the Department of Research and Education Management in SKH, who will quarterly monitor the progress and review the quality and completeness of data. All data will be stored at encrypted password-protected storage devices owned by SKH, and only the research team members have the access to view, manage, and analyze. Nurses who recruit participants and conduct baseline survey and research assistants will be responsible for identifying and recruiting participants, obtaining informed written consent, and performing double data entry. A formal data monitoring committee will not be considered for the conduct of this study as this is a low-risk intervention; however, the study will be annually reviewed by the Ethics Committee Review Board in SKH.

Ethics and dissemination

The study protocol (10th May2021, version 1.1) has received approval from the Ethics Committee Review Board of SKH, and any violations of the study protocol will be recorded and reported to the board.

The findings of the study will be disseminated through peer-reviewed scientific journals and conference presentations. A conclusion report will be submitted to the

National Natural Science Foundation of China and the Shenzhen Municipal Health Commission.

Patient and public partnership involvement

In this study, we will apply the CBPR principles which allow patients, family members and mental health service providers to participate in developing and evaluating the intervention strategy against post-discharge suicide.

Discussion

To our knowledge, this study is the first implementation study in China to recruit a sizable number of in-hospitalized patients with psychotic symptoms and MDD in a community-based participatory setting and a continuum of mental health care aiming to decrease post-discharge suicide risk. We believe the results may provide implementational evidence for stakeholders in China on reducing post-discharge suicide risk for psychiatric patients in resource-limited areas.

Interventions that reduce post-discharge suicide risk among psychiatric patients usually apply BCIs, psychological therapies (i.e., behavior therapy, cognitive therapy, and behavior cognitive therapy), medication treatment, case management, and assertive community treatment (ACT)[18 90 91]. Though interventions like case management and ACT are effective to prevent post-discharge suicide, they are more viable and practical in countries/regions with adequate mental health and social resources, and it is not suitable for widespread implementation in China, where there

are about 2.20 psychiatric professionals per 100,000 persons including psychiatrists and community mental health workers[92 93]. In Shenzhen, there are 2.50 psychiatric professionals per 100,000 persons, which is lower than that in Canada (14.68), the U.S. (10.54) and Japan (11.87) [92 94]. Hence, it is necessary to explore implementation effectiveness of low-cost interventions like BCIs in China.

Short length of stay, side effects of medication treatments, low treatment adherence, history of suicide attempts, and hospitalization and discharge experiences were associated with increased suicide risk among discharged psychiatric patients [95]. Meanwhile, studies also report the loneliness, feelings of lost and uncertainty would increase post-discharge suicide risk: a) patients are aware of suicide risk, but they don't know how to manage it and neither how nor whom to ask for help; b) without doctor's or nurse's orders/advice, patients may lose daily goals and don't know what to do after discharge; c) patients may actively avoid contact with others and feel lonely even if others take the initiative to care; d) patients may experience self-blame and self-guilt; e) patients may experience frustrations in recovery[23-25]. These studies not only provide a context that explain the high post-discharge suicide risk among psychiatric patients, but also indicate the importance of social connectedness and social support that BCIs could deliver to decrease the risk.

This study has several strengths. First, it addresses the continuum of mental health care from clinic to post-discharge settings and emphasizes on social connectedness and social support. Second, the study focuses on implementation outcomes. We will

not only focus on the decrease of post-discharge suicide risk but also the acceptability, adoption, fidelity, efficiency, safety, equity, and patient-centeredness, etc. Third, the study will apply the CBPR framework to develop a culturally tailored and locally contextual intervention strategy, which will fully consider benefits of all stakeholders (patients and family members, clinic, and community mental health service providers) in post-discharge suicide risk management. Fourth, we will apply the SMART design to explore the effect of BCIs on decreasing post-discharge suicide risk and to determine the best frequency to deliver BCIs. The SMART design could improve validity by allowing simultaneous evaluation of the results of different interventions or combinations of interventions, reduce dropouts by reassigning participants who are not sensitive to the initial intervention or do not have the desired outcome to another intervention, examine what intervention participants have received and when, and promise all participants receive interventions[62-64].

Although this study may hold promise for better implementation, service and client outcomes, there are potential limitations. Though we will have a sample size with the power to detect outcomes, we will only recruit patients with psychotic symptoms and MDD who cannot be the represent all patients discharged from psychiatric settings, while the setting of the study is in Shenzhen that may not represent the entire China. As a type-1 hybrid design implementation study, there are outcomes predominantly being evaluated by qualitative interviews, including feasibility and acceptability, which may not fully represent the implementation in

practice. Thus, the generalizability of our findings will be limited.

Trial Registration and status

This study has been registered in the ClinicalTrials.gov registry on May 31, 2021 (NCT04907669). The anticipated recruitment date for the CBPR study will be September 1, 2021, and the anticipated recruitment date for the SMART trial will be January 1, 2022.

List of abbreviations:

ACER: Average Cost-Effectiveness Ratio;

ACT: Assertive Community Treatment;

BCIs: Brief Contact Interventions;

BSI-CV: The Beck Suicide Ideation Scale-Chinese Version;

CBPR: Community-based participatory research;

CI: Confidence interval;

DSSI: The Duke Social Support Index;

IOF:The Implementation Outcome Framework;

ITT: Intent-to-treat;

LHSs: Lay health care supporters;

M.I.N.I.: The Mini-International Neuropsychiatric Interview;

MDD: Major depressive disorder;

OR: Odds ratio;

RCT: Randomized controlled trial;

SCS: The Social Connectedness Scale;

SD: Standard Deviation;

SMART: Sequential Multiple Assignment Randomized Trial

SKH: Shenzhen Kangning Hospital

SPIRIT: the Standard Protocol Items for Randomized Trials;

WHO: The World Health Organization.

References

1. Phillips MR, Li X, Zhang Y. Suicide rates in China, 1995–99. *The Lancet* 2002;359(9309):835-40. doi: 10.1016/s0140-6736(02)07954-0
2. Liu Z, Huang Y, Ma C, et al. Suicide rate trends in China from 2002 to 2015. *Chinese Mental Health Journal* 2017;31(10):756-67.
3. Jiang H, Niu L, Hahne J, et al. Changing of suicide rates in China, 2002–2015. *Journal of Affective Disorders* 2018;240:165-70. doi: 10.1016/j.jad.2018.07.043
4. National Health Commission of the People's Republic of China. Yearbook of Health in the People's Republic of China. Beijing: Peking Union Medical College Press 2018.
5. World Health Organization. Global Health Observatory (GHO) data 2017. Available from: https://www.who.int/gho/mental_health/suicide_rates/en/ Accessed at June 28th 2020.
6. Goldacre M, Seagroatt V, Hawton K. Suicide after discharge from psychiatric inpatient care. *The Lancet* 1993;342(8866):283-86. doi: 10.1016/0140-6736(93)91822-4
7. Geddes JR, Juszczak E. Period trends in rate of suicide in first 28 days after discharge from psychiatric hospital in Scotland, 1968-92. *BMJ* 1995;311(7001):357-60. doi: 10.1136/bmj.311.7001.357
8. Appleby L, Shaw J, Amos T, et al. Suicide within 12 months of contact with mental health services: national clinical survey. *BMJ* 1999;318(7193):1235-39. doi: 10.1136/bmj.318.7193.1235
9. Meehan J, Kapur N, Hunt IM, et al. Suicide in mental health in-patients and within 3 months of discharge. *British Journal of Psychiatry* 2006;188(2): 129-134.
10. Hunt IM, Kapur N, Webb R, et al. Suicide in recently discharged psychiatric patients: a case-control study. *Psychological Medicine* 2009;39(3):443-49.

11. Bickley H, Hunt IM, Windfuhr K, et al. Suicide within two weeks of discharge from psychiatric inpatient care: a case-control study. *Psychiatric Services* 2013;64(7):653-59. doi: 10.1176/appi.ps.201200026
12. World Health Organization, Preventing suicide: A global imperative. 2014: World Health Organization. Available from https://www.who.int/mental_health/suicide-prevention/world_report_2014/en/. Assessed at September 19th 2019.
13. Chung DT, Ryan CJ, Hadzi-Pavlovic D, et al. Suicide rates after discharge from psychiatric facilities: a systematic review and meta-analysis. *JAMA Psychiatry* 2017;74(7):694. doi: 10.1001/jamapsychiatry.2017.1044
14. Haglund A, Lysell H, Larsson H, et al. Suicide immediately after discharge from psychiatric inpatient care: a cohort study of nearly 2.9 million discharges. *Journal of Clinical Psychiatry* 2019;80(2) doi: 10.4088/JCP.18m12172
15. Chung D, Hadzi-Pavlovic D, Wang M, et al. Meta-analysis of suicide rates in the first week and the first month after psychiatric hospitalisation. *BMJ Open* 2019;9(3):e023883. doi: 10.1136/bmjopen-2018-023883
16. National health commission of People's Republic of China.the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 Edition): National health commission of People's Republic of China 2018. Available from http://www.nhc.gov.cn/jkj/s7932/201806/90d5fe3b7f48453db9b9beb85dfdc8a8.shtml. Accessed at September 23rd 2019.
17. Fleischmann A, Bertolote JM, Wasserman D, et al. Effectiveness of brief intervention and contact for suicide attempters: a randomized controlled trial in five countries. *Bulletin of the World Health Organization* 2008;86:703-09.
18. Zalsman G, Hawton K, Wasserman D, et al. Suicide prevention strategies revisited: 10-year systematic review. *The Lancet Psychiatry* 2016;3(7):646-59. doi: https://doi.org/10.1016/S2215-0366(16)30030-X
19. Riblet NBV, Shiner B, Young-Xu Y, et al. Strategies to prevent death by suicide: Meta-analysis of randomised controlled trials. *British Journal of Psychiatry* 2017;210(6):396-402. doi: 10.1192/bjp.bp.116.18779
20. Luxton DD, June JD, Comtois KA. Can postdischarge follow-up contacts prevent suicide and suicidal behavior? *Crisis* 2013;34(1):32-41.
21. Falcone G, Nardella A, Lamis DA, et al. Taking care of suicidal patients with new technologies and reaching-out means in the post-discharge period. *World Journal of Psychiatry* 2017;7(3):163-76. doi: 10.5498/wjp.v7.i3.163
22. Messiah A, Notredame CE, Demarty AL, et al. Combining green cards, telephone calls and postcards into an intervention algorithm to reduce suicide reattempt (AlgoS): P-hoc analyses of an inconclusive randomized controlled trial. *PloS One* 2019;14(2):e0210778.
23. Motto JA, Bostrom AG. A Randomized Controlled Trial of Postcrisis Suicide Prevention. *Psychiatric Services* 2001;52(6):828-33. doi:

10.1176/appi.ps.52.6.828
24. Cutcliffe JR, Links PS, Harder HG, et al. Understanding the risks of recent discharge: the phenomenological lived experiences – "Existential Angst at the Prospect of Discharge". *Crisis* 2012;33(1):21-29. doi: 10.1027/0227-5910/a000096
25. Riblet N, Shiner B, Scott R, et al. Exploring psychiatric inpatients' beliefs about the role of post-discharge follow-up care in suicide prevention. *Military Medicine* 2019;184(1-2):e91-e100.
26. Hare-Duke L, Dening T, de Oliveira D, et al. Conceptual framework for social connectedness in mental disorders: systematic review and narrative synthesis. *Journal of Affective Disorders* 2019;245:188-99. doi: https://doi.org/10.1016/j.jad.2018.10.359
27. Motto JA. Suicide prevention for high-risk persons who refuse treatment. *Suicide and Life-Threatening Behavior* 1976;6(4):223-30.
28. Carter GL, Clover K, Whyte IM, et al. Postcards from the EDge project: randomised controlled trial of an intervention using postcards to reduce repetition of hospital treated deliberate self poisoning. *BMJ* 2005;331(7520):805. doi: 10.1136/bmj.38579.455266.E0
29. Carter GL, Clover K, Whyte IM, et al. Postcards from the EDge: 24-month outcomes of a randomised controlled trial for hospital-treated self-poisoning. *British Journal of Psychiatry* 2007;191(6):548-53. doi: 10.1192/bjp.bp.107.038406
30. Cebrià AI, Parra I, Pàmias M, et al. Effectiveness of a telephone management programme for patients discharged from an emergency department after a suicide attempt: controlled study in a Spanish population. *Journal of affective disorders* 2013;147(1-3):269-76.
31. Hassanian-Moghaddam H, Sarjami S, Kolahi A-A, et al. Postcards in Persia: a twelve to twenty-four month follow-up of a randomized controlled trial for hospital-treated deliberate self-poisoning. *Archives of Suicide Research* 2017;21(1):138-54. doi: 10.1080/13811118.2015.1004473
32. Comtois KA, Kerbrat AH, DeCou CR, et al. Effect of Augmenting standard care for military personnel with brief caring text messages for suicide prevention: a randomized clinical trial. *JAMA Psychiatry* 2019;76(5):474-83. doi: 10.1001/jamapsychiatry.2018.4530
33. Zhang S, Zhou G. Intervention of violent and suicidal behaviour of mental patients in the community. *Journal of Clinical Psychological Medicine* 1999;9(2):77-78.
34. Fu Y, Shen J,Dang W, et al. Effects of psychological intervention on the young people of attempted suicide. *Chinese Mental Health Journal* 2007;21(8):571-74.
35. Bi B. Intervention for emergency department patients who attempt suicide in ShenYang general hospital: an 1-year follow-up study. China Medical

University, 2010.

36. Xu D, Zhang X, Li X, et al. Effectiveness of 18-month psychosocial intervention for suicide attempters. *Chinese Mental Health Journal* 2012;26(1):24-29.

37. Chen W-J, Ho C-K, Shyu S-S, et al. Employing crisis postcards with case management in Kaohsiung, Taiwan: 6-month outcomes of a randomised controlled trial for suicide attempters. *BMC Psychiatry* 2013;13(1):191.

38. Zhao W, Peng M, Zhao Y, et al. The mechanism of assertive community treatment effects on the suicidality in schizophrenia patients. *Chinese Journal of Clinical Psychology* 2018;26(3):620-23.

39. Yuan Q, Qian M, Tao L. The effect of individualized information support on suicidal attitude in patients with depressive disorder. *Chinese Primary Health Care* 2019;33(2):45-48.

40. Cotgrove A, Zirinsky L, Black D, et al. Secondary prevention of attempted suicide in adolescence. *Journal of Adolescence* 1995;18(5):569-77.

41. Evans J, Evans M, Morgan HG, et al. Crisis card following self-harm: 12-month follow-up of a randomised controlled trial. *British Journal of Psychiatry* 2005;187(2):186-87.

42. Vaiva G, Walter M, Al Arab AS, et al. ALGOS: the development of a randomized controlled trial testing a case management algorithm designed to reduce suicide risk among suicide attempters. *BMC Psychiatry* 2011;11(1):1. doi: 10.1186/1471-244X-11-1

43. Reger MA, Luxton DD, Tucker RP, et al. Implementation methods for the caring contacts suicide prevention intervention. *Professional Psychology: Research and Practice* 2017;48(5):369-77. doi: 10.1037/pro0000134

44. Yuan Y, Wang G, Shen L, et al. The effect of suicide risk for implementing hospital-community-family integrated care in depression patients. *Chinese Nursing Research* 2016;30(11):4174-76.

45. Tetzlaff, J.M., Moher, D. & Chan, AW. Developing a guideline for clinical trial protocol content: Delphi consensus survey. *Trials* 2012;l13:176. https://doi.org/10.1186/1745-6215-13-176

46. Tong A, Sainsbury P & Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care* 2007; 19(6): 349-357.

47. Xiao S, Zhou L, Xu H. Suicide prevention and crisis intervention -the concept and certification of suicide. *Journal of Clinical Psychiatry* 2005;15(5):298-99.

48. Balas EA, Boren SA. Managing clinical knowledge for health care improvement. *Yearbook of Medical Informatics* 2000;9(01):65-70.

49. Grant J, Green L, Mason B. Basic research and health: a reassessment of the scientific basis for the support of biomedical science. *Research Evaluation* 2003;12(3):217-24.

50. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question:

understanding time lags in translational research. *Journal of the Royal Society of Medicine* 2011;104(12):510-20.
51. Eccles MP, Mittman BS. Welcome to Implementation Science. *Implementation Science* 2006;1(1):1. doi: 10.1186/1748-5908-1-1
52. Bauer MS, Damschroder L, Hagedorn H, et al. An introduction to implementation science for the non-specialist. *BMC Psychology* 2015;3(1):32-32. doi: 10.1186/s40359-015-0089-9
53. Proctor EK, Landsverk J, Aarons G, et al. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Administration and Policy in Mental Health and Mental Health Services Research* 2009;36(1):24-34.
54. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* 2011;38(2):65-76.
55. Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care* 2012;50(3):217-26. doi: 10.1097/MLR.0b013e3182408812
56. Statistics Bureau of Shenzhen Municipality. Shenzhen Statistical Yearbook 2019. Beijing: China Satatistics Press Co. 2019.
57. Hu J, Hu C, Duan W, et al. Survey on mental disorders among registered residents and non-registered residents in Shenzhen. *Chinese Journal of Epidemiology* 2009;30(6):543-48.
58. Huang Y, Wang Y, Wang H, et al. Prevalence of mental disorders in China: a cross-sectional epidemiological study. *The Lancet Psychiatry* 2019;6(3):211-24. doi: 10.1016/S2215-0366(18)30511-X
59. Israel BA, Schulz AJ, Parker EA, et al. Review of community-based research: assessing partnership approaches to improve public health. *Annual Review of Public Health* 1998;19(1):173-202.
60. Israel BA, Schulz AJ, Parker EA, et al. Community-based participatory research: policy recommendations for promoting a partnership approach in health research. *Education for Health* 2001;14(2):182-97.
61. Smikowski J, Dewane S, Johnson ME, et al. Community-based participatory research for improved mental health. *Ethics & Behavior* 2009;19(6):461-78.
62. Murphy SA. An experimental design for the development of adaptive treatment strategies. *Statistics in Medicine* 2005;24(10):1455-81.
63. Lei H, Nahum-Shani I, Lynch K, et al. A "SMART" design for building individualized treatment sequences. *Annual Review of Clinical Psychology* 2012;8:21-48.
64. Wallace MP, Moodie EE, Stephens DA. SMART thinking: a review of recent developments in sequential multiple assignment randomized trials. *Current*

Epidemiology Reports 2016;3(3):225-32.

65. Tencent Holdings Ltd. The 2020 First Quarter Results 2020. Available from: https://cdc-tencent-com-1258344706.image.myqcloud.com/uploads/2020/05/18/fc1afc176e4604f3a05602a467b259ad.pdf. Accessed at July 28th 2020.
66. Crivello A, Levy J, Murphy S. Statistical methodology for a smart design in the development of adaptive treatment strategies: University Park, PA: The Pennsylvania State University, The Methodology Center, 2007.
67. Cohen J. Statistical power analysis for the behavioural sciences. Hillsdale, NJ: Laurence Erlbaum Associates: Inc, 1988.
68. R: A language and environment for statistical computing [program], 2013.
69. Li X, Phillips MR, Zhang Y, et al. Reliability and validity of the Chinese version of Beck Scate for Suicide Ideation (BSI-CV) among university students. *Chinese Mental Health Journal* 2011;25(11):862-66
70. He H, Yang Y. Path analysis on the influencing factors of suicide ideation among college students in Beijing. *Chinese Journal of School Health* 2015;36(1):80-83.
71. Ai M, Chen JM, Wang MJ, et al. The impulsiveness and aggression among suicide attempters in college students. *Chinese Journal of Nervous and Mental Diseases* 2011;37(11):650-55
72. Zhou ZJ, Yang xi, Liu TB, et al. Influencing factors to suicide behaviors among adolescent students of four schools in Shenzhen. *Chinese Journal of School Health* 2015;36(9):1330-33.
73. Beck AT, Steer RA, Ranieri WF. Scale for suicide ideation: psychometric properties of a self-report version. *Journal of Clinical Psychology* 1988;44(4):499-505. doi: 10.1002/1097-4679(198807)44:4<499::aid-jclp2270440404>3.0.co;2-6
74. Li X, Phillips MR, Tong YS, et al. Reliability and validity of the Chinese version of Beck Suicide Ideation Scale (BSI-CV) in adult community residents. *Chinese Mental Health Journal* 2010;24(4):250-55.
75. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *The Journal of Clinical Psychiatry* 1998;58(Suppl 20):22–33.
76. Si T, Shu L, Dang W, et al. Evaluation of the Reliability and Validity of Chinese Version of the Mini.International Neuropsychiatric Interview in Patients with Mental Disorders. *Chinese Mental Health Journal* 2009;23(7):493-97,503.
77. Lecrubier Y, Sheehan DV, Weiller E, et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to the CIDI. *European Psychiatry* 1997;12(5):224-31.
78. Fan X, Wei J, Zhang J. On Reliability and validity of Social Connectedness

Scale-Revised in Chinese middle school students. *Journal of Southwest China Normal University (Natural Science Edition)* 2015;40(8):118-22.
79. Lee RM, Robbins SB. Measuring belongingness: the social connectedness and the social assurance scales. *Journal of Counseling Psychology* 1995;42(2):232.
80. Koenig HG, Westlund RE, George LK, et al. Abbreviating the Duke Social Support Index for use in chronically ill elderly individuals. *Psychosomatics* 1993;34(1):61-9. doi: 10.1016/s0033-3182(93)71928-3
81. Zhou M, Qiu J, Mou Y, et al. Reliability and validity of the 23-Duke Social Support Scale among rural elderly population. *Chinese Journal of Public Health* 2015;31(11):1369-72.
82. Hou F, Cerulli C, Wittink M, et al. Depression, social support and associated factors among women living in rural China: a cross-sectional study. *BMC Women's health* 2015;15(1):28.
83. Zhang J, Conwell Y, Wieczorek WF, et al. Studying Chinese suicide with proxy-based data: reliability and validity of the methodology and instruments in China. *Journal of Nervous and Mental Disease* 2003;191(7):450.
84. Jia C, Zhang J. Psychometric characteristics of the Duke Social Support Index in a young rural Chinese population. *Death Studies* 2012;36(9):858-69.
85. Link BG, Struening EL, Neese-todd S, et al. On describing and seeking to change the experience of stigma. *Psychiatric Rehabilitation Skills* 2002;6(2):201-31. doi: 10.1080/10973430208408433
86. Xu H. A study of stigma of people with Schizophrenia and relationship with medication compliance. Peking Union Medical College, 2008.
87. Zhang JX, Schwarzer R. Measuring optimistic self-beliefs: A Chinese adaptation of the General Self-Efficacy Scale. *Psychologia: An International Journal of Psychology in the Orient* 1995;38(3):174–181.
88. Liamputtong P. Researching the vulnerable: A guide to sensitive research methods: Sage 2006.
89. Liamputtong P. Qualittive Research Methods. Fourth ed. Australia: Oxford University Press 2013:218-237.
90. Inagaki M, Kawashima Y, Kawanishi C, et al. Interventions to prevent repeat suicidal behavior in patients admitted to an emergency department for a suicide attempt: a meta-analysis. *Journal of Affective Disorder*s 2015;175:66-78.
91. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies: a systematic review. *JAMA* 2005;294(16):2064-74.
92. World Health Organization. Global Health Observatory data repository 2019. Available from http://apps.who.int/gho/data/?theme=main. Assessed at October 23rd 2019.
93. Zhao W, Zhu Y, Luo XW, et al. The assertive community treatment model for severe mental disorders: A review. Chinese Mental Health Journal

2014;28(2):89-96.
94. Shenzhen Mental Health Center. Shenzhen Mental Health Work Information Brief Shenzhen: Shenzhen Mental Health Center, 2020.
95. Schechter M, Goldblatt MJ, Ronningstam E, et al. Postdischarge suicide: a psychodynamic understanding of subjective experience and its importance in suicide prevention. *Bulletin of the Menninger Clinic* 2016;80(1):80-96.

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Contributors All authors contributed to the conceptualization and the design of this study. FH obtained the funding and contributed to the theoretical framework of the study. FH and HL conceived the prototype of the intervention, the study design, and the creation of the team. HL and GC drafted the initial manuscript together. JL and CH provided the sampling, randomization, and analytical strategy. BZ and YB conceived the content of the intervention and provided crisis intervention service in the study. LS, CC and HX contributed to the implementation of the study. TL and EDC steered the direction of the study and contributed significantly to the revision of the manuscript. All authors read and revised the initial manuscript and approved the final version.

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Competing interests All authors declare no competing interest.

Ethics approval Ethics Committee Review Board of Shenzhen Kangning Hospital (2021-K006-01-1).

Data sharing statement We will make quantitative data publicly available through FigShare 12 months after the main studies are published in peer-reviewed journals. The data will contain unidentified demographic information, primary and secondary outcomes, and other covariate outcomes. Please contact the PI to request for the use of the data, and the requests should include detail contact information of applicants, the purpose of study, and the analysis plan.

Table 1 The definition of suicide behaviors in this study

Suicide behaviors	Definition
Suicidal ideation	Having a clear intent to harm oneself without a clear plan, nor taking any preparation or actions.
Suicidal plan	Having a clear plan to harm oneself without taking any preparation or actions.
Suicidal preparation	Taking any preparation to commit suicide without taking actions to harm oneself.
Attempted suicide	Taking actions to commit suicide with a certain intensity of wish to die, which did not directly result in a fatal outcome.
Completed suicide	Taking actions to commit suicide with a certain wish to die and directly resulting in death

Figure caption:

Figure 1 The Implementation Outcomes Framework

Figure 2 The summary of the study design

Figure 3 The SMART design trial

Figure 4 An example of the brief contact intervention delivered through WeChat

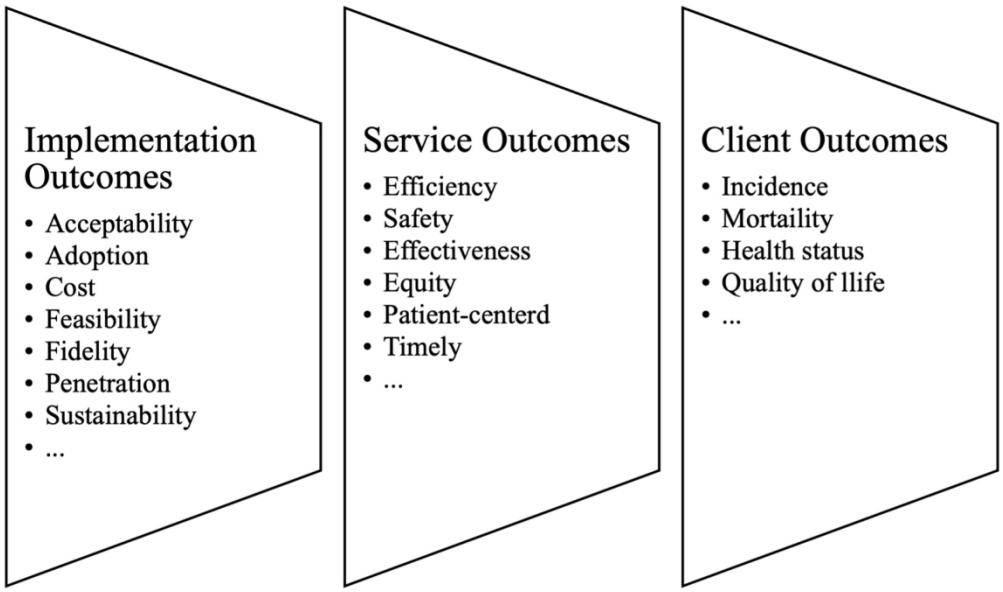

Figure 1 The Implementation Outcomes Framework

153x90mm (300 x 300 DPI)

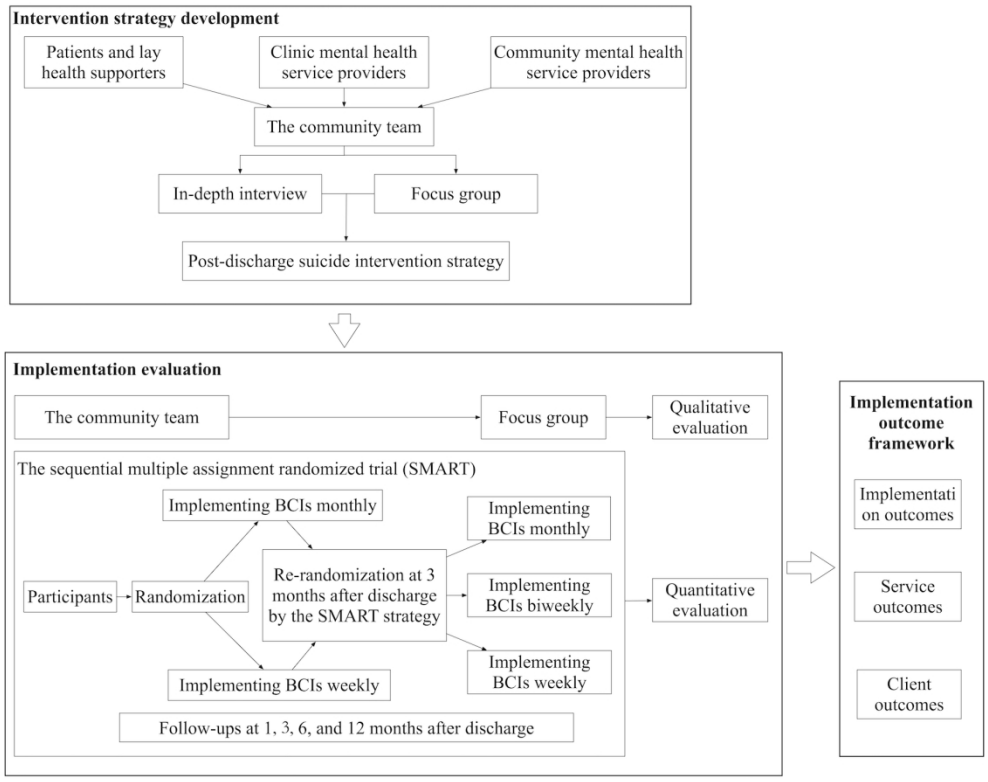

Figure 2 Summary of the study design

162x127mm (300 x 300 DPI)

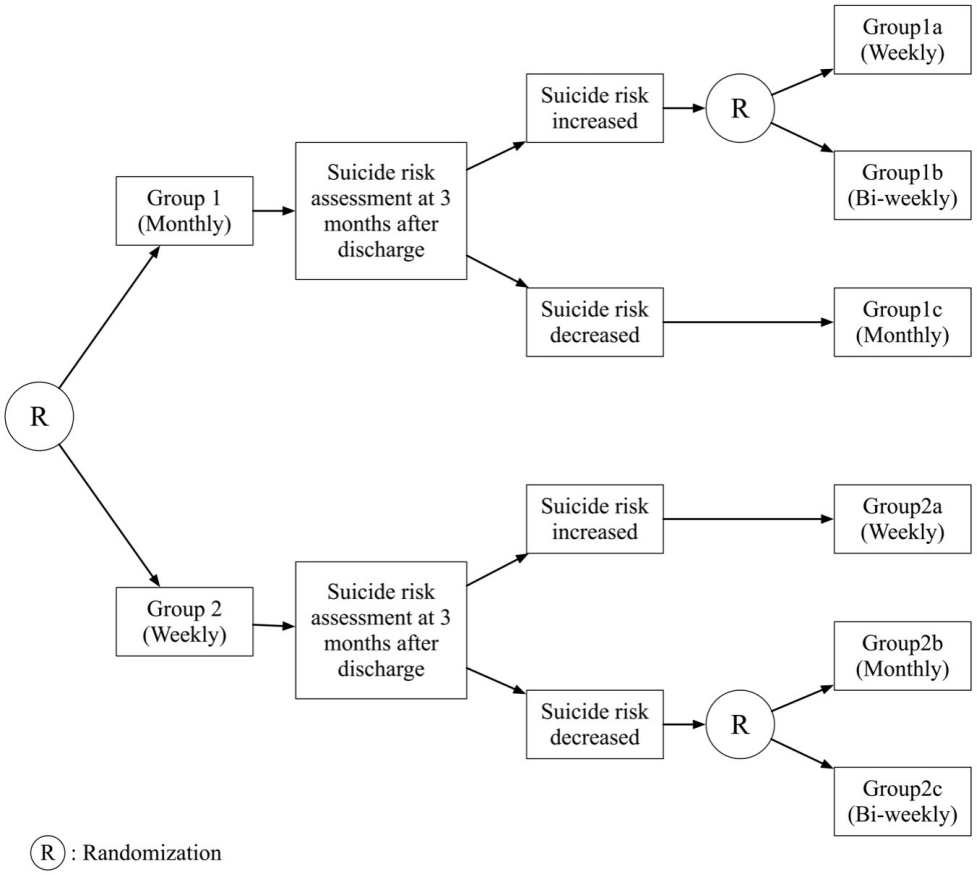

Figure 3 The SMART design trial

159x141mm (220 x 220 DPI)

Figure 4 An example of the brief contact intervention delivered through WeChat

368x330mm (300 x 300 DPI)

Interview Guide Questions for Intervention Development
(For patients)

1. What is the biggest problem you might face after discharge?

2. From your opinion, what might cause relapses after discharge?

3. From your opinion, what might increase suicide risk after discharge?

4. For the problems mentioned, what kind of help do you need?

5. How would you like clinical and community mental health providers to help? Please explain your expectations as well.

6. We are considering implementing follow-ups to reduce suicide risk after discharge, and what kind of follow-up services do you prefer?

7. Brief contact interventions (BCIs) are a series of low cost and non-intrusive interventions to maintain long-term contact with patients, and we plan to use BCIs to deliver the follow-ups patients and their lay health supporters. What content do you prefer or expect from the contacts?

8. What's the appropriate frequency to contact you?

9. Will the BCIs make you more willing to pay regular visits to out-patient clinics? Please explain to us.

10. In general, what is the most important to reduce suicide risk after discharge?

11. Do you feel less connected to others during hospitalization?

12. If you have been hospitalized before, have you experienced any loss of social connectedness after discharge?

13. Are you worried about having less connectedness after discharge now?

14. Under what circumstances would you feel more connected to others?

15. Do you receive any help and support during hospitalization? What are they?

16. If you have been hospitalized before, have you experienced any loss of support after discharge?

17. Are you worried about having less support after discharge now?

18. Under what circumstances would you feel more supported?

In-depth/Focus Group Interview Guide Questions for Intervention Development (Lay health supporters)

1. What is the biggest problem the patient might face after discharge?

2. From your opinion, what might cause their relapses after discharge?

3. From your opinion, what might increase their suicide risk after discharge?

4. For the problems mentioned, what kind of help do you and/or the patient need?

5. How would you like clinical and community mental health providers to help you and the patient? Please explain your expectations as well.

6. We are considering implementing follow-ups to reduce suicide risk after discharge, and what kind of follow-up services do you prefer?

7. Brief contact interventions (BCIs) are a series of low cost and non-intrusive interventions to maintain long-term contact with patients, and we plan to use BCIs to deliver the follow-ups to patients and their lay health supporters. What content do you prefer or expect from the contacts?

8. What's the appropriate frequency to contact you or the patient?

9. Will the BCIs make the patient more willing to pay regular visits to out-patient clinics? Please explain to us.

10. In general, what is the most important to reduce suicide risk after discharge?

11. Do you feel the patient is less connected to others during hospitalization?

12. If the patient has been hospitalized before, did he or she experience any loss of social connectedness after discharge?

13. Are you worried about the patient having less connectedness after discharge?

14. Under what circumstances would the patient feel more connected to others?

15. Does the patient receive help and support during hospitalization?

16. If the patient has been hospitalized before, did he or she experience any loss of support after discharge?

17. Are you worried about the patient having less support after discharge?

18. Under what circumstances would the patient feel more supported?

In-depth/Focus Group Interview Guide Questions for Intervention Development (Clinic and community mental health service providers)

1. Is there a need for suicide risk management in mental health services?

2. Is it necessary to focus on reducing suicide risk among psychiatric patients after discharge? Please explain to us.

3. How would you implement post-discharge suicide risk management from your perspective?

4. Please briefly introduce your experience in patient suicide risk management.

5. Have there been any incidents of suicides or threats of suicide by patients? If yes, how did you handle it and what do you learn from it? If no, how would you handle it?

6. In general, what is the most pressing need to reduce suicide risk after discharge?

7. We are considering implementing follow-ups to reduce suicide risk after discharge, and what kind of follow-up services will you suggest?

8. Brief contact interventions (BCIs) are a series of low cost and non-intrusive interventions to maintain long-term contact with patients, and we plan to use BCIs to deliver the follow-ups to patients and their lay health supporters. What content would you like to deliver?

9. What's the appropriate frequency to contact patients?

10. Will the BCIs make patients more willing to pay regular visits to out-patient clinics? Please explain to us.

11. How to improve social connectedness and social support for patients through such intervention?

12. How to increase patients' follow-up visits to out-patient clinic, increase compliance and acceptance of follow-ups through such intervention?

13. What would patients' and lay health supporters' attitudes be towards the acceptance and adoption of the suicide risk intervention? Please explain to us.

14. How to be patient-centered in such intervention?

15. Is there any potential risk to patients when implementing the BCIs?

In-depth/Focus Group Interview Guide Questions for Intervention Evaluation (Patients and lay health supporters)

1. What's your attitude toward the acceptability of implementing brief contact interventions (BCIs) to reduce post-discharge suicide risk? Please explain to us.

2. Do you think BCIs are feasible in daily lives? Please explain to us.

3. After discharge, will you adopt BCIs to reduce suicide risk? Please explain to us.

4. Do you think BCIs pose potential risk or harm to the patients?

5. What do you think about the equity of BCIs? Please explain to us.

6. As we have introduced BCIs, including the content, the way to implement and the frequency to contact patients, do you think BCIs are patient-centered and fully taking account of your needs and feelings? Please explain to us.

7. Do you have any suggestions of implementing BCIs to reduce post-discharge suicide risk among psychiatric patients?

In-depth/Focus Group Interview Guide Questions for Intervention Evaluation (Clinic and community mental health service providers)

1. Do you accept to implement brief contact interventions (BCIs) as a routine service for discharged psychiatric patients?

2. Do you think BCIs are feasible in your daily work? Please explain to us.

3. Will you adopt BCIs to reduce suicide risk after discharge in follow-ups? Please explain your opinions to us.

4. Do you think BCIs pose potential risk or harm to the patients?

5. Would you please share your opinions about how BCIs reduce post-discharge suicide risk among psychiatric patients?

6. What do you think about the equity of BCIs? Please explain to us.

7. As we have introduced BCIs, including the content, the way to implement and the frequency to contact patients, do you think BCIs are patient-centered and fully taking account of your needs and feelings?

8. Will implementing BCIs meet your needs in your work related to suicide risk management?

9. Do you have any suggestions of implementing BCIs to reduce post-discharge suicide risk among psychiatric patients?

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_4 , 29 , clinicaltrials.gov _____
	2b	All items from the World Health Organization Trial Registration Data Set	__Not applicable_____
Protocol version	3	Date and version identifier	__26_____
Funding	4	Sources and types of financial, material, and other support	__37_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1, 2, 36_____
	5b	Name and contact information for the trial sponsor	_2_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_36_____

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_25_____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_6-9_____
	6b	Explanation for choice of comparators	__15,16_____
Objectives	7	Specific objectives or hypotheses	_9_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_12-16,18_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_11,12_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_14,16,17_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_15,_18_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_15_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_19___ _____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	__Not applicable_

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_19-23_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_15,16_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_13,17_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_19_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_18_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_18_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_18_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_18_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_Not applicable_____
Methods: Data collection, management, and analysis			

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_19_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_19_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_19,25_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_23,24_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_23,24_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_25_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_Not applicable_
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_Not applicable_
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_Not applicabl _
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__26_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_Not applicable_
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_25_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_Not applicable_
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_37_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_37_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_25,37_____ _
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_Not applicable__
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_26_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_Not applicable__
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_37____ ____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Not applicable__

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_Not applicable__

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated.

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	15
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	N/A
Gender	4	Was the researcher male or female?	N/A
Experience and training	5	What experience or training did the researcher have?	15
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	N/A
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	N/A
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	26
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	14
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	14
Sample size	12	How many participants were in the study?	14,15
Non-participation	13	How many people refused to participate or dropped out? Reasons?	N/A
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	15
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	N/A
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	N/A
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplement file
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	15
Field notes	20	Were field notes made during and/or after the inter view or focus group?	15
Duration	21	What was the duration of the inter views or focus group?	N/A
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	26
Description of the coding tree	25	Did authors provide a description of the coding tree?	N/A
Derivation of themes	26	Were themes identified in advance or derived from the data?	N/A
Software	27	What software, if applicable, was used to manage the data?	26
Participant checking	28	Did participants provide feedback on the findings?	14
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	N/A
Data and findings consistent	30	Was there consistency between the data presented and the findings?	N/A
Clarity of major themes	31	Were major themes clearly presented in the findings?	N/A
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	N/A

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

BMJ Open

A sequential multiple assignment randomized trial of a brief contact intervention for suicide risk management among discharged psychiatric patients: an implementation study protocol

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Primary Subject Heading:	Public health
Secondary Subject Heading:	Mental health, Global health, Qualitative research
Keywords:	PSYCHIATRY, Suicide & self-harm < PSYCHIATRY, QUALITATIVE RESEARCH, STATISTICS & RESEARCH METHODS

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A sequential multiple assignment randomized trial of a brief contact intervention for suicide risk management among discharged psychiatric patients: an implementation study protocol

Huiming Liu Ph.D.[1, *], Guanjie Chen M.D.[1, *], Jinghua Li Ph.D.[2], Chun Hao Ph.D.[2], Bin Zhang M.S.[1], Yuanhan Bai M.S.[3], Liangchen Song M.S.[1], Chang Chen M.S.[1], Haiyan Xie M.S.[1], Tiebang Liu M.D.[1], Eric D. Caine M.D.[4], Fengsu Hou Ph.D.[1, 2, #]

1. Department of Public Health, Shenzhen Kangning Hospital/Shenzhen Mental Health Center

Address: No.1080 Cuizhu Road, Luohu District, Shenzhen Guangdong, China, 518020

2. Sun Yat-sen Global Health Institute, School of Public Health, Sun Yat-sen University

Address: No. 74 Zhongshan 2nd Road, Guangzhou, Guangdong China, 510080.

3. Department of Bipolar Disorders, Shenzhen Kangning Hospital/Shenzhen Mental Health Center (Pingshan Campus)

Address: No.77 Zhenbi Road, Pingshan District, Shenzhen Guangdong, China, 518118

4. Department of Psychiatry, University of Rochester Medical Center

Address: 601 Elmwood Ave, Box PSYCH, Rochester, NY, USA 14642

* Co-first authors

Correspondent author

Email Address:

Huiming Liu: huimingcsu@163.com

Guanjie Chen: chen_guan_jie@hotmail.com

Jinghua Li: lijinghua3@mail.sysu.edu.cn

Chun Hao: haochun@mail.sysu.edu.cn

Bin Zhang: johnbean_604@aliyun.com

Yuanhan Bai: baiyuanhan@163.com

Liangchen Song: SLC136823221043@126.com

Chang Chen: 807810612@qq.com

Haiyan Xie: 251309219@qq.com

Tiebang Liu: liutbsz@126.com

Eric D. Caine: eric_caine@urmc.rochester.edu

Fengsu Hou: houfengsu@gmail.com

Corresponding author and trial sponsor

Fengsu Hou, Address: Shenzhen Kangning Hospital/Shenzhen Mental Health Center, No.1080 Cuizhu Road, Luohu District, Shenzhen Guangdong, China, 518020. Telephone number: +86-0755-25533524. Email: houfengsu@gmail.com

Word account: 5577

Abstract:

Introduction

The post-discharge suicide risk among psychiatric patients is significantly higher than it is among patients with other diseases and general population. The brief contact interventions (BCIs) are recommended to decrease suicide risk in areas with limited mental health service resources like China. This study aims to develop a post-discharge suicide intervention strategy based on BCIs and evaluate its implementability under the Implementation Outcome Framework.

Methods and analysis

This study will invite psychiatric patients and family members, clinical and community mental health service providers as the community team to develop a post-discharge suicide intervention strategy. The study will recruit 312 patients with psychotic symptoms and 312 patients with major depressive disorder discharged from Shenzhen Kangning Hospital (SKH) in a Sequential Multiple Assignment Randomized Trial. Participants will be initially randomized into two intervention groups to receive BCIs monthly and weekly, and they will be re-randomized into three intervention groups to receive BCIs monthly, bi-weekly and weekly at 3 months after discharge according to the change of their suicide risk. Follow-ups are scheduled at 1, 3, 6 and 12 months after discharge. With the Intent-to-treat approach, generalized estimating equation and survival analysis will be applied. This study will also collect qualitative and quantitative information on implementation and service

outcomes from the community team.

Ethics/dissemination

This study has received ethical approval from the Ethics Committee Review Board of SKH. All participants will provide written informed consent prior to enrollment. The findings of the study will be disseminated through peer-reviewed scientific journals, conference presentations. A project report will be submitted to the National Natural Science Foundation of China as the concluding report of this funded project, and to the mental health authorities in the Shenzhen to refine and apply evidence-based and pragmatic interventions into health systems for post-discharge suicide prevention.

Trial registration number: NCT04907669

Keywords Psychiatric patients, Post-discharge suicide, Brief contact interventions, Sequential multiple assignment randomized trial, Implementation science

Strengths and limitations

1. To our knowledge, this is the first mix-methods study in China evaluating the implementation of an evidence-based intervention which reduces post-discharge suicide risk among psychiatric patients.

2. A well-designed sequential multiple assignment randomized trial (SMART) is

embedded to investigate the effectiveness of the brief contact intervention reducing post-discharge suicide risk among psychiatric patients.

3. The community-based participatory research approach will be applied to develop the intervention strategy and to evaluate implementation outcomes.

4. Although the sample size of SMART is well calculated and powered by previous studies, it is modest.

Introduction

Suicide is an acknowledged global public health concern. In China, the annual average suicide rate decreased from 23 per 100,000 people between 1995 and 1999 to 6.75 per 100,000 people between 2012 and 2015[1-3]. In 2017, as the fifth leading cause of death, the reported suicide rate in China was 4.31 and 7.66 per 100,000 people in urban and rural, respectively[4]. In comparison, the World Health Organization (WHO) reported the global rate was 10.5 per 100,000 people in 2016[5].

Patients discharged from psychiatric settings carry substantially greater risk for suicide. The pooled rate of suicide among discharged psychiatric patients was 484 per 100,000 person-years within 12 months worldwide, and it was 2950, 2060 and 1132 per 100,000 person-years within 1 week, 1 month and 3 months, respectively[6-15]. We know of only one study involving persons of Chinese ethnicity, which found a rate of 1062 per 100,000 people during the year following discharge in Hong Kong, where community mental health services (influence by programs in the UK and in Australia) have been funded far more generously and, thus, been more resourceful in services than those in mainland China[8].

There is no specific mental health policy in China with respect to psychiatric patients at risk of post-discharge suicide. For patients with severe mental disorders in China, which include schizophrenia, schizoaffective disorder, paranoid psychosis, bipolar disorder, psychotic disorders due to epilepsy, or intellectual developmental disorder with psychotic disorders, they will receive follow-ups from community

mental health workers after discharge according to the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 Edition)[16]. In specific, the Code requires psychiatric facilities to report and register all patients with severe mental disorders in the Information Management System for Severe Mental Disorders, in which the patients will be rated from level 0 to 5 for the risk of violent behaviors. Registered patients will be rated as level 4 if conducted self-harm or attempted suicide, and the Code requires psychiatrists, family doctors, community mental health workers, mental health social workers, and the police to conduct joint follow-ups at least once every two weeks for patients at level 3 to 5. However, the follow-ups focus on the risk of violent behaviors towards the public rather than post-discharge suicide.

For patients with other mental disorders, registrations in the system and joint follow-ups are not required. Psychiatrists may occasionally report individual patients with non-severe mental disorders who are at risk for suicide to the information system as appropriate; and once reported, community mental health workers must conduct follow-ups in accordance with the Code focusing on suicide risk and related mental disorder symptoms. Other patients with suicide risk who are not reported will rely on active visit to out-patient clinics or contracting psychological crisis workers for post-discharge suicide interventions.

Brief contact interventions (BCIs) are evidence-based and have been recommended to decrease post-discharge suicide risk in areas of limited mental

health resources[12 17-19]. BCIs are a series of non-intrusive interventions at low cost aiming to develop long term contact with discharged psychiatric patients by phone calls, caring letters, postcards, text messages, emergency green cards and crisis cards, etc. [19-22]. The key is to send messages to discharged patients (as well as their spouses and family members, relatives, friends, and colleagues) at a predetermined frequency expressing greetings, encouragement, caring and support, and reminding them of psychological crisis assistance and mental health services. The proposed hypothesis of BCIs decreasing the post-discharge suicide risk is to increase patients' social connectedness and social support after discharge[23-26].

The WHO reported BCIs could decrease the post-discharge suicide risk among psychiatric patients effectively (OR=0.20, 95%CI: 0.09~0.42), and recommended integrating BCIs in the suicide intervention framework[12]. In a randomized controlled trial (RCT) study, Motto et al. reported the incidence of post-discharge suicide among intervention group was 8.48% (33/389) comparing with 14.10% (64/454) in control group[27]; however, in the followed 15-year cohort study, the significance of differences in post-discharge suicide incidence between groups wore off after five years[23]. Similar RCT studies reported BCIs could decrease suicide ideation, the number of suicide attempts, the risk of self-harm and suicide death[17 28-32]. In China, studies usually applied BCIs as one component of comprehensive suicide intervention strategies, in which health education, consulting, assertive community treatment, and case management were also included, and reported effectiveness in

reducing repeated attempted suicide, violent behaviors, and improving compliance to treatments[33-39]. However, few studies reported inconsistencies about the effectiveness of BCIs reducing post-discharge suicide ideation, attempts and deaths, which can be explained by different delivering frequencies (weekly, bi-weekly, monthly, or quarterly), types of BCIs (calls, caring cards, emails, or letters) and major outcomes (improvement of psychiatric symptoms, compliance to medication, or post-discharge suicide)[37 40-44].

In summary, most studies implemented BCIs monthly. Though few of them increased the delivering frequency from the first week to the first month after discharge, the frequency was reduced to monthly or bi-monthly, which could consequently be insufficient to maintain the effect on reducing post-discharge suicide risk in a long term. Hence, we hypothesize that BCIs with more intense delivering frequencies might work better for Chinese psychiatric patients than BCIs delivered monthly. Meanwhile, most of the content and the implementation strategy were predetermined by researchers rather than patients' needs and expectations. BCIs aim to reduce post-discharge suicide by increasing social connectedness and social support, but current studies did not measure the improvement of the two mediators or other confounding factors including socioeconomic factors, stigma, physical health, and the use of mental health service, etc. Further, studies only evaluated the effectiveness and did not evaluate the feasibility and sustainability in daily work.

Hence, our specific aims include: 1) to develop an intervention strategy against

post-discharge suicide risk for Chinese psychiatric patients based on BCIs; 2) to determine the best delivering frequency of BCIs for Chinese discharged psychiatric patients based on Sequential Multiple Assignment Randomized Trial; 3) to evaluate its implementability under the Implementation Outcome Framework (IOF).

Methods and analysis

This protocol has been written in accordance with the SPIRIT (Standard Protocol Items for Randomized Trials) statement and COREQ (Consolidated Criteria for Reporting Qualitative Research) checklist[45 46].

In this study, we will adopt the definition of suicide behaviors in a behavioral continuum proposed by Professor Shuiyuan Xiao in the Chinese cultural context (Table 1)[47]. We define suicide risk as the probability of an individual's death by suicide over a given time interval reflected by the intensity and frequency of suicide ideation, suicide plan, suicide preparation, and suicide attempts. Suicide risk will be evaluated by the Beck Suicide Ideation Scale-Chinese Version (BSI-CV) and the suicidality module of the Mini-International Neuropsychiatric Interview (M.I.N.I-Suicidality).

Insert Table 1 here.

Prior study

We conducted a prior study in Shenzhen Kangning Hospital (SKH) in early 2019. During January 1st to March 31st, there were 1,349 discharged patients who aged 18

years and above, diagnosed with mental disorders based on the International Classification of Diseases 10th Revision (ICD-10)[48], with ID, residence, and source of income, and had been hospitalized for 3 days at least, and 689 of them were diagnosed with suicide risk at admission. Of 689 patients, 515 of them completed the survey in a three-month follow-up. There were 20 attempted suicide cases and five completed suicide deaths, and the rate was 3883.5 (20/515) and 970.9 (5/515) per 100,000 people, respectively.

Implementation science framework

Evidence-based interventions and practices are poorly implemented, and it could take up to 17 years to adopt and integrate the interventions and practices into routine work by practitioners and policymakers[49-51]. To close the know-do gap and accelerate the implementation, implementation science aims to develop systematic methods and strategies to identify and address key points that promote or impede the process[52 53]. We adopt the Implementation Outcomes Framework (IOF) that evaluates implementation strategies by implementation outcomes, service outcomes and client outcomes, including acceptability, sustainability, fidelity, efficiency, effectiveness, satisfaction, and function etc. (Figure 1)[54 55]. Based on IOF, we identify this study as a type-1 hybrid design implementation study that determines effectiveness and explores the context of routine implementation[56].

Insert Figure 1 here.

Study setting

This study will be implemented in SKH, a public psychiatric hospital in Shenzhen City with over 1500 in-patient beds, 11,590 person-time of in-patients, and 369,000 person-time out-patient visits in 2020. Despite there are general hospitals providing psychiatric out-patient services in Shenzhen, SKH is the only medical facility providing in-patient psychiatric services. Shenzhen is with a population of 13.03 million residents, in which 8.48 million are internal migrants of varied sociodemographic features cross China[57]. The reported life-time prevalence of any mental disorders (excluding dementia) in Shenzhen was 21.87%, and the life-time prevalence of any mood disorders and any anxiety disorders was 9.62% and 14.45%[58]. In comparison, the life-time prevalence of any mental disorders (excluding dementia), any mood disorders and any anxiety disorders was 16.60%, 7.40% and 7.60% in China, respectively[59].

Study design

This is a mixed-methods study with two stages (Figure 2). The first stage is to develop the intervention strategy by in-depth and focus group interviews; and the second stage is to implement the strategy and evaluate the implementation quantitatively by a randomized trial and qualitatively by focus group interviews. The anticipated start and end dates for the study are September 1st 2021 and June 30th 2023.

Insert Figure 2 here.

The community-based participatory research

We aim to recruit discharged psychiatric patients and their lay health care supporters (LHSs) who are usually family members, psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers as the community team that will provide a Chinese context under the community-based participatory research (CBPR) framework[60-62]. In specific, the framework would help this study:

- explore the feasibility of implementing BCIs against suicide risk after discharge,
- understand the needs for suicide risk management after discharge from related health care service providers and acceptors,
- integrate suicide risk management experiences from the community,
- discuss, develop, and revise the intervention strategy with the community.

We categorize the community team into three sub-groups, the patients-LHSs group and the clinic mental health service provider group (psychiatrists and nurses, and psycho-crisis intervention team members) which will be recruited from SKH, and the community mental health service provider group (community mental health workers and mental health social workers) which will be recruited from eight community health centers in Shenzhen.

Intervention development

We will conduct three focus group interviews with each sub-group. To avoid bias in focus group interviews and to protect privacy related to personal experience in suicide and suicide intervention, we will also conduct ten to fifteen cases of in-depth interview in total with members from each sub-group. The themes include: 1) key points in suicide risk management after discharge, 2) how to develop BCIs content and deliver BCIs appropriately and feasibly to increase social connectedness and social support, 3) how to improve compliance to treatment and increase subsequent visits after discharge. There will be scheduled meetings with the community to discuss and revise the intervention strategy before implementation.

Implementation evaluation

Based on IOF, we will conduct three focus group interviews in each sub-group to explore 1) patients' and LHSs' attitudes, acceptability, and understanding of the strategy, 2) the clinic and community mental health service providers' willingness, feasibility, and sustainability to implement the strategy, 3) the effectiveness, efficiency, equity, safety and timeliness of the strategy and whether it is patient-centered.

The qualitative study sample

Purposive sampling will be applied to recruit participants face-to-face for the

community team. For each sub-group, there will be five to eight members. The inclusion criteria for the clinic and community mental health service provider groups are: 1) being 18 years and above, 2) having practiced in mental health service at least for 12 months. The inclusion criteria for the patients-LHSs group will be illustrated later. All participants will receive 100 Yuan (about $15.42) to offset their efforts and cost of taking part.

The qualitative data collection

All co-authors from SKH have qualitative research experience and will conduct focus group and in-depth interviews in privacy-protected meeting rooms of SKH. There will be an interviewer, a recorder of field note, and an observer for interviews. The interviewer will introduce the aims of the study, the purpose of the interview and obtain written informed consent including audio recording consent before interviews begin (Supplement file 1). The interview guide questions are showed in supplementary file (Supplement file 2). Audio recordings and field notes will be transcribed into text for analysis.

The sequential multiple assignment randomized trial

We will conduct the sequential multiple assignment randomized trial (SMART) to determine the best frequency to implement BCIs and investigate the patient outcomes in IOF. The SMART design reflects the idea of adaptive treatment strategies and dynamic treatment regimens that provide a sequence of decisions

about the points at which to offer different interventions and a set of intervention options for each decision point[63-65]. There will be two stages (Figure 3).

Stage 1: After recruitment and baseline survey, participants will be randomized into Group 1 and Group 2 where BCIs will be implemented monthly and weekly, respectively. Because suicide risk is the highest in the first three months among discharged psychiatric patients, we set the check point at three months after discharge to assess participants' suicide risk in both groups.

Stage 2: At the check point, for participants in Group 1, if the suicide risk increased, they will be re-randomized into Group 1a and Group 1b where BCIs will be implemented weekly and bi-weekly, respectively; if the suicide risk decreased or did not change, they will remain receiving BCIs monthly as Group 1c. For participants in Group 2, if the suicide risk increased or did not change, they will remain receiving BCIs weekly as Group 2a; if the suicide risk decreased, they will be re-randomized into Group 2b and Group 2c where BCIs will be implemented monthly and bi-weekly, respectively. After the re-randomization, participants will continue to receive BCIs until 12 months after discharge, and the suicide risk will be evaluated at 1, 3, 6 and 12 months after discharge.

In this study, the magnitude of change in the total score of the BSI-CV or M.I.N.I-Suicidality that determines re-randomization is 1 and above.

Insert Figure 3 here.

The quantitative study sample

We plan to implement the strategy in patients with psychotic symptoms and patients with major depressive disorder (MDD), as in representative of severe and non-severe mental disorders.

The inclusion criteria for patients are: 1) being 18 years and above, 2) being diagnosed with psychotic symptoms or MDD based on the ICD-10, 3) having received inpatient care for three days or more, 4) living in Shenzhen and having no plan to leave Shenzhen in the following 12 months after discharge, and 5) being able to read text messages, answer phone calls on mobile phones, use WeChat or any application on smart phones. WeChat is the most widely used app in China with about 11 billion active users in the first quarter of 2020[66]. Considering participants' suicide risk, we will also recruit their LHSs to receive BCIs at the same frequency. The inclusion criteria are: 1) being 18 years and above, 2) without diagnosis of any mental disorder, 3) being the main lay health care supporter for the patient, 4) living in Shenzhen and having no plan to leave Shenzhen in the following 12 months after discharge, and 5) being able to read text messages, answer phone calls on mobile phones, use WeChat, or any application on smart phones. All participants will receive 100 Yuan (about $15.42) to offset their efforts and cost of taking part.

Patients who are with cognitive impairment that prevents providing written informed consent due to either dementia or current psychosis episodes and who are with no ID, stable residence nor any source of income will be excluded. Particularly,

patients discharged on families' or patients' demand against medical advice will be excluded.

Sample size

The sample size was calculated to estimate the primary effect between Group 1 and Group 2 in the trial[67]. We set the rate of type I error α at 0.05, the rate of type II error β at 0.20, the power (1-β) at 0.80, the moderate effect size d at 0.35[68], and the sample size is 130 for each group, 260 in total; considering dropout, we will increase the sample size by 20%, and the final sample size is 312 participants. We will conduct two SMART trials in patients with psychotic symptoms and MDD separately, and the sample size for each trial is 312 (624 patients in total). We aim to recruit participants from January 1st 2022 until the sample size is reached.

Randomization and mask

After recruitment and the baseline survey, we will assign participants into Group 1 and Group 2 by block randomization in R program[69]. At the check point in the SMART trial, we will re-assign participants into Group 1a, Group 1b, Group 1c, Group 2a, Group 2b, and Group 2c based on their suicide risk by simple randomization in R program. The allocation ratio in randomization will be 1:1. The randomization will be performed by a statistician in the research team. Patients, LHSs, nurses who perform recruitment and baseline survey, the statistician who performs randomization, and investigators who perform follow-ups will be blinded

to the assignment.

Brief contact intervention

The BCI in this study is a series of structured messages, and it will primarily be delivered through pushing feeds on WeChat due to its popularity in China, and an iOS/Android application will also be applied to deliver the intervention. If participants did not use smartphones, messages will be delivered by mobile text messages or by phone calls. Though the content of messages is yet to be determined by the CBPR study, we expect to structure messages into six components including introduction, greetings for previous complaints, mental health promotion, encouragement and coping strategies, remind of treatment and subsequent visit, and crisis intervention resource. Noted, the same messages will also be sent to LHSs. Figure 4 shows an example of the brief contact intervention delivered through WeChat.

Insert Figure 4 here.

Quantitative data collection

To evaluate post-discharge suicide risk more cautiously and to provide crisis intervention in time, we will conduct face-to-face interview to collect information. After research assistants introduce the study and obtain written informed consent, trained nurses in SKH will recruit participants and perform baseline survey before discharge. As mentioned, we encourage subsequent visits to SKH out-patient clinics

in BCIs, and research assistants will contact participants to schedule out-patient visits and complete follow-up surveys during the visits at 1, 3, 6 and 12 months after discharge. If participants refused follow-ups in out-patient settings, we would schedule home visits to complete the survey by research assistants and community mental health workers. If patients did not respond, research assistants will contact their LHSs to obtain participants' recent updates and help them schedule out-patient visits for patients if necessary. Dropout is defined as 1) participants or their LHSs request to quit the study and stop receiving any brief contact messages; 2) participants or their LHSs refuse follow-up surveys either at out-patient clinics or at home; 3) participants pass away by accidents or other health problems except suicide. Particularly, at each time point of follow-ups, we will contact patients and LHSs up to three times. If neither of them responded, they would be treated as dropout.

Study outcomes and measurements

The study outcomes are based on the Implementation Outcomes Framework.

Implementation outcomes

Acceptability and *adoption* will be evaluated by the community's attitudes generating from qualitative interviews. *The adoption rate* will be measured by the number of participants who subscribe to follow the study's WeChat Platform or the iOS/Android smartphone application divided by the number of participants who remain as followers at the end of the study.

Feasibility will be evaluated by mental health service providers' attitudes generated from qualitative interviews.

Cost will be measured by the total cost of implementing the SMART trial, which will be recorded to assess the economic benefits of the intervention during the study.

Fidelity will be measured by a staged checklist that evaluates the degree to which the study is implemented as described in the protocol, the quality, and the competence of the study.

Sustainability will be evaluated by mental health service providers' attitudes generated from qualitative interviews.

Service outcomes

Efficiency will be measured by the number of daily brief contacts delivered to participants through WeChat, the application, text messages, and phone calls during implementation.

Safety that whether implementing BCIs would be any potential harm/danger to patients will be evaluated by the community's attitudes generated from qualitative interviews.

Effectiveness will be measured by the comparison of the trajectories of suicide ideation and suicidality from baseline to 3 and 12 months after discharge between Group 1 and Group 2, respectively.

Equity will be evaluated by the community in focus group interviews that how the

intervention strategy considers and address the disparities in social groups.

Patient-centeredness be evaluated by the community in focus group interviews that how well the intervention strategy considers and meets the needs and demands of patients, and whether the strategy fully considers participants' feelings.

Timeliness will be measured by the time that the research team cost to respond to participants' feedbacks and requests for crisis intervention.

Client outcomes

The trajectories of suicide risk (suicide ideation and suicidality) from baseline to 3- and 12-month post-discharge are the primary outcomes. The trajectories of suicide risk from 3-month to 12-month post-discharge are the secondary outcomes. The trajectories of social connectedness and social support from baseline to 3- and 12-month post-discharge are the secondary outcomes.

Suicide ideation will be measured by the Beck Suicide Ideation Scale-Chinese Version (BSI-CV), which has been translated and modified in the Chinese context, and it has been validated and widely applied in China[70-75]. The BSI-CV includes 19 items evaluating specific attitudes, ideations, behavior and plans to commit suicide during the past week, and each item scores from 0 to 2 with a total score ranging from 0 to 38, and a higher score indicates higher level of suicide risk.

Suicidality will be measured by the suicidality module of the Mini-International Neuropsychiatric Interview (M.I.N.I.-Suicidality), which has been validated in China,

to assess suicide risk for in- and out- patients, we will also evaluate participants' suicidality by this scale[76-78]. In the 6-item scale, dichotomous items ("No" or "Yes") evaluate wish to be dead, self-hurt, suicide ideation, plan, current and ever attempts during the past month, and "yes" to each item is assigned to score 1, 2, 6, 10, 10 and 4, respectively, with a higher total score indicating higher level of suicide risk.

Social connectedness will be measured by the Social Connectedness Scale (SCS) to evaluate participants' social connected ness after discharge, which has been validated in China[79 80]. The SCS is a 20-item scale, and each item is on a 6-Likert continuum (from "Strongly disagree" to "Strongly agree") scoring from 1 to 6[80]. A higher total score indicates a higher level of social connectedness.

Social support will be measured by the 23-item Duke Social Support Index (DSSI) to evaluate participants' social support after discharge[81]. The Chinese version of DSSI has been validated and applied in China[82-85]. The DSSI investigates social support by social interaction, perceived social support, and instrumental social support. Every answer has been assigned a score, and the total reflects the sum of the items ranging from 11 to 45. A higher total score indicates a higher level of social support.

Covariates

We will develop a questionnaire to collect information about covariates, and the questionnaire will be validated in pilot.

Demographic information will be collected at baseline by self-made questionnaire including age, marital status, occupation, income, Hukou (household residence registration), and residence time in Shenzhen.

Times of re-hospitalization for mental disorders will be measured by responses to the question "How many times have you been hospitalized for mental disorders?" in follow-ups.

The usage of crisis intervention will be measured by the responses to the question "How many times have you called the research team or the Crisis Intervention Hotline for help after discharged from hospital?" in follow-ups.

Perceived stigma will be evaluated by the Chinese version of Link Perceived Devaluation-Discrimination Scale [86 87]. The scale contains 12 items assessing the extent to which a person believes that other people will devalue or discriminate against someone with a mental illness. Each item is on a 4-Likert continuum (from "Strongly disagree" to "Strongly agree") scoring from 1 to 4. A higher total score indicates a higher level of perceived stigma. The trajectories of patients' perceived stigma from baseline to 3- and 12- month after discharge will be analyzed.

Self-efficacy will be evaluated by the Chinese version of the General Self-Efficacy Scale[88]. The scale contains 10 items, and each item is on a 4-Likert continuum (from "Not at all true" to "Exactly true") scoring from 1 to 4. A higher total score indicates a higher level of self-efficacy. The total score's trajectory from baseline to three months after discharge will be recorded and compared. The trajectories of patients'

self-efficacy from baseline to 3- and 12- month after discharge will be analyzed.

Compliance to treatment will be evaluated by a 4-item self-administered questionnaire. The questionnaire inquires whether the patients take medications under the instruction on prescriptions. Each item is on a 4-Likert continuum (from "Not following the instruction" to "Exactly following the instruction") scoring from 1 to 4. A higher total score indicates a higher level of compliance to treatment. The change of patients' compliance from baseline to 3- and 12- month after discharge will be analyzed.

Statistical analyses

We will perform the in analyses. Demographic and baseline information between participants in Group 1 and Group 2, as well as between participants with psychotic symptoms and MDD, will be presented in the form of mean (standard deviation, SD), the 95% confidence intervals (CIs) for continuous variables, and percentages for categorical variables.

We will use independent t-test (for continuous variables) and Chi-square test (categorical variables) to compare the differences between groups. We will use Generalized Estimating Equation (GEE) to explore the time-trends/trajectories of repeated measured outcomes and adjust for potential confounding variables.

We will use survival analyses (SA) to compare the effect of BCIs reducing post-discharge suicide risk at endpoint between participants in Group 1 and Group 2, as

well as between patients with psychotic symptoms and MDD. The model will take mediating factors into account. We will run pair-wise comparisons between re-assigned groups by GEE ([Group1a+Group1c] vs. [Group1b+Group1c] vs. [Group2a+Group2b] vs. [Group2a+Group2c]). And we will use path analysis to validate the hypothesis that BCIs could decrease post-discharge suicide risk by increasing social connectedness and social support. Further, we plan to use the Bootstrap percentile method to calculate the Average Cost-Effectiveness Ratio (ACER) that reflects the cost of reducing one unit of post-discharge suicide risk (one unit of score in BSI-CV and M.I.N.I.-Suicidality).

Multiple imputation will be used to account for the missing values, assuming they are missing at random. We set statistical significance at 0.05 and all analyses will be two-sided. All data analyses will be performed in the R program[68].

Qualitative analyses

We will code the qualitative data into the categorical and numerical data with a three-step procedure, and then apply content analysis method to analyze data in R program[89 90].

Open coding Four coders will independently code the qualitative data into categorical and numerical codes, and share their codes. If the codes were different over the same response, there would be a discussion until reaching consensus.

Axial coding During analysis, the authors will associate codes to each other, and

re-conceptualized categories and sub-categories to fully elaborate codes.

Selective coding The authors will compare different categories of codes and examined the associations to identify a core category that could represent the key themes to research questions and related to other categories. The selective coding is at a higher level compared with axial coding, and the core category could be a new category created during analysis.

Lastly, we will enter the categorical and numerical data into a database for content analysis and generated the qualitative results.

Data monitoring and quality assurance

The study will receive overall supervision from the Department of Research and Education Management in SKH, who will quarterly monitor the progress and review the quality and completeness of data. All data will be stored at encrypted password-protected storage devices owned by SKH, and only the research team members have the access to view, manage, and analyze. Nurses who recruit participants and conduct baseline survey and research assistants will be responsible for identifying and recruiting participants, obtaining informed written consent, and performing double data entry. A formal data monitoring committee will not be considered for the conduct of this study as this is a low-risk intervention; however, the study will be annually reviewed by the Ethics Committee Review Board in SKH.

Ethics and dissemination

The study protocol (10th May2021, version 1.1) has received approval from the Ethics Committee Review Board of SKH, and any violations of the study protocol will be recorded and reported to the board.

The findings of the study will be disseminated through peer-reviewed scientific journals and conference presentations. A conclusion report will be submitted to the National Natural Science Foundation of China and the Shenzhen Municipal Health Commission.

Patient and public partnership involvement

In this study, we will apply the CBPR principles which allow patients, family members and mental health service providers to participate in developing and evaluating the intervention strategy against post-discharge suicide.

Discussion

To our knowledge, this study is the first implementation study in China to recruit a sizable number of in-hospitalized patients with psychotic symptoms and MDD in a community-based participatory setting and a continuum of mental health care aiming to decrease post-discharge suicide risk. We believe the results may provide implementational evidence for stakeholders in China on reducing post-discharge suicide risk for psychiatric patients in resource-limited areas.

Interventions that reduce post-discharge suicide risk among psychiatric patients

usually apply BCIs, psychological therapies (i.e., behavior therapy, cognitive therapy, and behavior cognitive therapy), medication treatment, case management, and assertive community treatment (ACT)[18 91 92]. Though interventions like case management and ACT are effective to prevent post-discharge suicide, they are more viable and practical in countries/regions with adequate mental health and social resources, and it is not suitable for widespread implementation in China, where there are about 2.20 psychiatric professionals per 100,000 persons including psychiatrists and community mental health workers[93 94]. In Shenzhen, there are 2.50 psychiatric professionals per 100,000 persons, which is lower than that in Canada (14.68), the U.S. (10.54) and Japan (11.87) [93 95]. Hence, it is necessary to explore implementation effectiveness of low-cost interventions like BCIs in China.

Short length of stay, side effects of medication treatments, low treatment adherence, history of suicide attempts, and hospitalization and discharge experiences were associated with increased suicide risk among discharged psychiatric patients [96]. Meanwhile, studies also report the loneliness, feelings of lost and uncertainty would increase post-discharge suicide risk: a) patients are aware of suicide risk, but they don't know how to manage it and neither how nor whom to ask for help; b) without doctor's or nurse's orders/advice, patients may lose daily goals and don’t know what to do after discharge; c) patients may actively avoid contact with others and feel lonely even if others take the initiative to care; d) patients may experience self-blame and self-guilt; e) patients may experience frustrations in recovery[23-25]. These studies

not only provide a context that explain the high post-discharge suicide risk among psychiatric patients, but also indicate the importance of social connectedness and social support that BCIs could deliver to decrease the risk.

This study has several strengths. First, it addresses the continuum of mental health care from clinic to post-discharge settings and emphasizes on social connectedness and social support. Second, the study focuses on implementation outcomes. We will not only focus on the decrease of post-discharge suicide risk but also the acceptability, adoption, fidelity, efficiency, safety, equity, and patient-centeredness, etc. Third, the study will apply the CBPR framework to develop a culturally tailored and locally contextual intervention strategy, which will fully consider benefits of all stakeholders (patients and family members, clinic, and community mental health service providers) in post-discharge suicide risk management. Fourth, we will apply the SMART design to explore the effect of BCIs on decreasing post-discharge suicide risk and to determine the best frequency to deliver BCIs. The SMART design could improve validity by allowing simultaneous evaluation of the results of different interventions or combinations of interventions, reduce dropouts by reassigning participants who are not sensitive to the initial intervention or do not have the desired outcome to another intervention, examine what intervention participants have received and when, and promise all participants receive interventions[63-65].

Although this study may hold promise for better implementation, service and client outcomes, there are potential limitations. Though we will have a sample size

with the power to detect outcomes, we will only recruit patients with psychotic symptoms and MDD who cannot be the represent all patients discharged from psychiatric settings, while the setting of the study is in Shenzhen that may not represent the entire China. As a type-1 hybrid design implementation study, there are outcomes predominantly being evaluated by qualitative interviews, including feasibility, acceptability, and sustainability, which may not fully represent the implementation in practice. Thus, the generalizability of our findings will be limited.

Trial Registration and status

This study has been registered in the ClinicalTrials.gov registry on May 31, 2021 (NCT04907669). The anticipated recruitment date for the CBPR study will be September 1, 2021, and the anticipated recruitment date for the SMART trial will be January 1, 2022.

List of abbreviations:

ACER: Average Cost-Effectiveness Ratio;

ACT: Assertive Community Treatment;

BCIs: Brief Contact Interventions;

BSI-CV: The Beck Suicide Ideation Scale-Chinese Version;

CBPR: Community-based participatory research;

CI: Confidence interval;

DSSI: The Duke Social Support Index;

IOF:The Implementation Outcome Framework;

ITT: Intent-to-treat;

LHSs: Lay health care supporters;

M.I.N.I.: The Mini-International Neuropsychiatric Interview;

MDD: Major depressive disorder;

OR: Odds ratio;

RCT: Randomized controlled trial;

SCS: The Social Connectedness Scale;

SD: Standard Deviation;

SMART: Sequential Multiple Assignment Randomized Trial

SKH: Shenzhen Kangning Hospital

SPIRIT: the Standard Protocol Items for Randomized Trials;

WHO: The World Health Organization.

References

1. Phillips MR, Li X, Zhang Y. Suicide rates in China, 1995–99. *The Lancet* 2002;359(9309):835-40. doi: 10.1016/s0140-6736(02)07954-0
2. Liu Z, Huang Y, Ma C, et al. Suicide rate trends in China from 2002 to 2015. *Chinese Mental Health Journal* 2017;31(10):756-67.
3. Jiang H, Niu L, Hahne J, et al. Changing of suicide rates in China, 2002–2015. *Journal of Affective Disorders* 2018;240:165-70. doi: 10.1016/j.jad.2018.07.043
4. National Health Commission of the People's Republic of China. Yearbook of Health in the People's Republic of China. Beijing: Peking Union Medical College Press 2018.
5. World Health Organization. Global Health Observatory (GHO) data 2017. Available from: https://www.who.int/gho/mental_health/suicide_rates/en/ Accessed at June 28th 2020.
6. Goldacre M, Seagroatt V, Hawton K. Suicide after discharge from psychiatric

inpatient care. *The Lancet* 1993;342(8866):283-86. doi: 10.1016/0140-6736(93)91822-4

7. Geddes JR, Juszczak E. Period trends in rate of suicide in first 28 days after discharge from psychiatric hospital in Scotland, 1968-92. *BMJ* 1995;311(7001):357-60. doi: 10.1136/bmj.311.7001.357
8. Appleby L, Shaw J, Amos T, et al. Suicide within 12 months of contact with mental health services: national clinical survey. *BMJ* 1999;318(7193):1235-39. doi: 10.1136/bmj.318.7193.1235
9. Meehan J, Kapur N, Hunt IM, et al. Suicide in mental health in-patients and within 3 months of discharge. *British Journal of Psychiatry* 2006;188(2): 129-134.
10. Hunt IM, Kapur N, Webb R, et al. Suicide in recently discharged psychiatric patients: a case-control study. *Psychological Medicine* 2009;39(3):443-49.
11. Bickley H, Hunt IM, Windfuhr K, et al. Suicide within two weeks of discharge from psychiatric inpatient care: a case-control study. *Psychiatric Services* 2013;64(7):653-59. doi: 10.1176/appi.ps.201200026
12. World Health Organization, Preventing suicide: A global imperative. 2014: World Health Organization. Available from https://www.who.int/mental_health/suicide-prevention/world_report_2014/en/. Assessed at September 19th 2019.
13. Chung DT, Ryan CJ, Hadzi-Pavlovic D, et al. Suicide rates after discharge from psychiatric facilities: a systematic review and meta-analysis. *JAMA Psychiatry* 2017;74(7):694. doi: 10.1001/jamapsychiatry.2017.1044
14. Haglund A, Lysell H, Larsson H, et al. Suicide immediately after discharge from psychiatric inpatient care: a cohort study of nearly 2.9 million discharges. *Journal of Clinical Psychiatry* 2019;80(2) doi: 10.4088/JCP.18m12172
15. Chung D, Hadzi-Pavlovic D, Wang M, et al. Meta-analysis of suicide rates in the first week and the first month after psychiatric hospitalisation. *BMJ Open* 2019;9(3):e023883. doi: 10.1136/bmjopen-2018-023883
16. National health commission of People's Republic of China.the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 Edition): National health commission of People's Republic of China 2018. Available from http://www.nhc.gov.cn/jkj/s7932/201806/90d5fe3b7f48453db9b9beb85dfdc8a8.shtml. Accessed at September 23rd 2019.
17. Fleischmann A, Bertolote JM, Wasserman D, et al. Effectiveness of brief intervention and contact for suicide attempters: a randomized controlled trial in five countries. *Bulletin of the World Health Organization* 2008;86:703-09.
18. Zalsman G, Hawton K, Wasserman D, et al. Suicide prevention strategies revisited: 10-year systematic review. *The Lancet Psychiatry* 2016;3(7):646-59. doi: https://doi.org/10.1016/S2215-0366(16)30030-X
19. Riblet NBV, Shiner B, Young-Xu Y, et al. Strategies to prevent death by suicide: Meta-analysis of randomised controlled trials. *British Journal of Psychiatry*

2017;210(6):396-402. doi: 10.1192/bjp.bp.116.18779
20. Luxton DD, June JD, Comtois KA. Can postdischarge follow-up contacts prevent suicide and suicidal behavior? *Crisis* 2013;34(1):32-41.
21. Falcone G, Nardella A, Lamis DA, et al. Taking care of suicidal patients with new technologies and reaching-out means in the post-discharge period. *World Journal of Psychiatry* 2017;7(3):163-76. doi: 10.5498/wjp.v7.i3.163
22. Messiah A, Notredame CE, Demarty AL, et al. Combining green cards, telephone calls and postcards into an intervention algorithm to reduce suicide reattempt (AlgoS): P-hoc analyses of an inconclusive randomized controlled trial. *PloS One* 2019;14(2):e0210778.
23. Motto JA, Bostrom AG. A Randomized Controlled Trial of Postcrisis Suicide Prevention. *Psychiatric Services* 2001;52(6):828-33. doi: 10.1176/appi.ps.52.6.828
24. Cutcliffe JR, Links PS, Harder HG, et al. Understanding the risks of recent discharge: the phenomenological lived experiences – "Existential Angst at the Prospect of Discharge". *Crisis* 2012;33(1):21-29. doi: 10.1027/0227-5910/a000096
25. Riblet N, Shiner B, Scott R, et al. Exploring psychiatric inpatients' beliefs about the role of post-discharge follow-up care in suicide prevention. *Military Medicine* 2019;184(1-2):e91-e100.
26. Hare-Duke L, Dening T, de Oliveira D, et al. Conceptual framework for social connectedness in mental disorders: systematic review and narrative synthesis. *Journal of Affective Disorders* 2019;245:188-99. doi: https://doi.org/10.1016/j.jad.2018.10.359
27. Motto JA. Suicide prevention for high-risk persons who refuse treatment. *Suicide and Life-Threatening Behavior* 1976;6(4):223-30.
28. Carter GL, Clover K, Whyte IM, et al. Postcards from the EDge project: randomised controlled trial of an intervention using postcards to reduce repetition of hospital treated deliberate self poisoning. *BMJ* 2005;331(7520):805. doi: 10.1136/bmj.38579.455266.E0
29. Carter GL, Clover K, Whyte IM, et al. Postcards from the EDge: 24-month outcomes of a randomised controlled trial for hospital-treated self-poisoning. *British Journal of Psychiatry* 2007;191(6):548-53. doi: 10.1192/bjp.bp.107.038406
30. Cebrià AI, Parra I, Pàmias M, et al. Effectiveness of a telephone management programme for patients discharged from an emergency department after a suicide attempt: controlled study in a Spanish population. *Journal of affective disorders* 2013;147(1-3):269-76.
31. Hassanian-Moghaddam H, Sarjami S, Kolahi A-A, et al. Postcards in Persia: a twelve to twenty-four month follow-up of a randomized controlled trial for hospital-treated deliberate self-poisoning. *Archives of Suicide Research* 2017;21(1):138-54. doi: 10.1080/13811118.2015.1004473

32. Comtois KA, Kerbrat AH, DeCou CR, et al. Effect of Augmenting standard care for military personnel with brief caring text messages for suicide prevention: a randomized clinical trial. *JAMA Psychiatry* 2019;76(5):474-83. doi: 10.1001/jamapsychiatry.2018.4530

33. Zhang S, Zhou G. Intervention of violent and suicidal behaviour of mental patients in the community. *Journal of Clinical Psychological Medicine* 1999;9(2):77-78.

34. Fu Y, Shen J,Dang W, et al. Effects of psychological intervention on the young people of attempted suicide. *Chinese Mental Health Journal* 2007;21(8):571-74.

35. Bi B. Intervention for emergency department patients who attempt suicide in ShenYang general hospital: an 1-year follow-up study. China Medical University, 2010.

36. Xu D, Zhang X, Li X, et al. Effectiveness of 18-month psychosocial intervention for suicide attempters. *Chinese Mental Health Journal* 2012;26(1):24-29.

37. Chen W-J, Ho C-K, Shyu S-S, et al. Employing crisis postcards with case management in Kaohsiung, Taiwan: 6-month outcomes of a randomised controlled trial for suicide attempters. *BMC Psychiatry* 2013;13(1):191.

38. Zhao W, Peng M, Zhao Y, et al. The mechanism of assertive community treatment effects on the suicidality in schizophrenia patients. *Chinese Journal of Clinical Psychology* 2018;26(3):620-23.

39. Yuan Q, Qian M, Tao L. The effect of individualized information support on suicidal attitude in patients with depressive disorder. *Chinese Primary Health Care* 2019;33(2):45-48.

40. Cotgrove A, Zirinsky L, Black D, et al. Secondary prevention of attempted suicide in adolescence. *Journal of Adolescence* 1995;18(5):569-77.

41. Evans J, Evans M, Morgan HG, et al. Crisis card following self-harm: 12-month follow-up of a randomised controlled trial. *British Journal of Psychiatry* 2005;187(2):186-87.

42. Vaiva G, Walter M, Al Arab AS, et al. ALGOS: the development of a randomized controlled trial testing a case management algorithm designed to reduce suicide risk among suicide attempters. *BMC Psychiatry* 2011;11(1):1. doi: 10.1186/1471-244X-11-1

43. Reger MA, Luxton DD, Tucker RP, et al. Implementation methods for the caring contacts suicide prevention intervention. *Professional Psychology: Research and Practice* 2017;48(5):369-77. doi: 10.1037/pro0000134

44. Yuan Y, Wang G, Shen L, et al. The effect of suicide risk for implementing hospital-community-family integrated care in depression patients. *Chinese Nursing Research* 2016;30(11):4174-76.

45. Tetzlaff, J.M., Moher, D. & Chan, AW. Developing a guideline for clinical trial protocol content: Delphi consensus survey. *Trials* 2012;l13:176. https://doi.org/10.1186/1745-6215-13-176

46. Tong A, Sainsbury P & Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care* 2007; 19(6): 349-357.
47. Xiao S, Zhou L, Xu H. Suicide prevention and crisis intervention -the concept and certification of suicide. *Journal of Clinical Psychiatry* 2005;15(5):298-99.
48. World Health Organization. The ICD-10 classification of mental and behavioural disorders: diagnostic criteria for research. Geneva: World Health Organization; 1993.
49. Balas EA, Boren SA. Managing clinical knowledge for health care improvement. *Yearbook of Medical Informatics* 2000;9(01):65-70.
50. Grant J, Green L, Mason B. Basic research and health: a reassessment of the scientific basis for the support of biomedical science. *Research Evaluation* 2003;12(3):217-24.
51. Morris ZS, Wooding S, Grant J. The answer is 17 years, what is the question: understanding time lags in translational research. *Journal of the Royal Society of Medicine* 2011;104(12):510-20.
52. Eccles MP, Mittman BS. Welcome to Implementation Science. *Implementation Science* 2006;1(1):1. doi: 10.1186/1748-5908-1-1
53. Bauer MS, Damschroder L, Hagedorn H, et al. An introduction to implementation science for the non-specialist. *BMC Psychology* 2015;3(1):32-32. doi: 10.1186/s40359-015-0089-9
54. Proctor EK, Landsverk J, Aarons G, et al. Implementation research in mental health services: an emerging science with conceptual, methodological, and training challenges. *Administration and Policy in Mental Health and Mental Health Services Research* 2009;36(1):24-34.
55. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. *Administration and Policy in Mental Health and Mental Health Services Research* 2011;38(2):65-76.
56. Curran GM, Bauer M, Mittman B, et al. Effectiveness-implementation hybrid designs: combining elements of clinical effectiveness and implementation research to enhance public health impact. *Medical Care* 2012;50(3):217-26. doi: 10.1097/MLR.0b013e3182408812
57. Statistics Bureau of Shenzhen Municipality. Shenzhen Statistical Yearbook 2019. Beijing: China Satatistics Press Co. 2019.
58. Hu J, Hu C, Duan W, et al. Survey on mental disorders among registered residents and non-registered residents in Shenzhen. *Chinese Journal of Epidemiology* 2009;30(6):543-48.
59. Huang Y, Wang Y, Wang H, et al. Prevalence of mental disorders in China: a cross-sectional epidemiological study. *The Lancet Psychiatry* 2019;6(3):211-24. doi: 10.1016/S2215-0366(18)30511-X

60. Israel BA, Schulz AJ, Parker EA, et al. Review of community-based research: assessing partnership approaches to improve public health. *Annual Review of Public Health* 1998;19(1):173-202.
61. Israel BA, Schulz AJ, Parker EA, et al. Community-based participatory research: policy recommendations for promoting a partnership approach in health research. *Education for Health* 2001;14(2):182-97.
62. Smikowski J, Dewane S, Johnson ME, et al. Community-based participatory research for improved mental health. *Ethics & Behavior* 2009;19(6):461-78.
63. Murphy SA. An experimental design for the development of adaptive treatment strategies. *Statistics in Medicine* 2005;24(10):1455-81.
64. Lei H, Nahum-Shani I, Lynch K, et al. A "SMART" design for building individualized treatment sequences. *Annual Review of Clinical Psychology* 2012;8:21-48.
65. Wallace MP, Moodie EE, Stephens DA. SMART thinking: a review of recent developments in sequential multiple assignment randomized trials. *Current Epidemiology Reports* 2016;3(3):225-32.
66. Tencent Holdings Ltd. The 2020 First Quarter Results 2020. Available from: https://cdc-tencent-com-1258344706.image.myqcloud.com/uploads/2020/05/18/fc1afc176e4604f3a05602a467b259ad.pdf. Accessed at July 28th 2020.
67. Crivello A, Levy J, Murphy S. Statistical methodology for a smart design in the development of adaptive treatment strategies: University Park, PA: The Pennsylvania State University, The Methodology Center, 2007.
68. Cohen J. Statistical power analysis for the behavioural sciences. Hillsdale, NJ: Laurence Erlbaum Associates: Inc, 1988.
69. R: A language and environment for statistical computing [program], 2013.
70. Li X, Phillips MR, Zhang Y, et al. Reliability and validity of the Chinese version of Beck Scate for Suicide Ideation (BSI-CV) among university students. *Chinese Mental Health Journal* 2011;25(11):862-66
71. He H, Yang Y. Path analysis on the influencing factors of suicide ideation among college students in Beijing. *Chinese Journal of School Health* 2015;36(1):80-83.
72. Ai M, Chen JM, Wang MJ, et al. The impulsiveness and aggression among suicide attempters in college students. *Chinese Journal of Nervous and Mental Diseases* 2011;37(11):650-55
73. Zhou ZJ, Yang xi, Liu TB, et al. Influencing factors to suicide behaviors among adolescent students of four schools in Shenzhen. *Chinese Journal of School Health* 2015;36(9):1330-33.
74. Beck AT, Steer RA, Ranieri WF. Scale for suicide ideation: psychometric properties of a self-report version. *Journal of Clinical Psychology* 1988;44(4):499-505. doi: 10.1002/1097-4679(198807)44:4<499::aid-jclp2270440404>3.0.co;2-6

75. Li X, Phillips MR, Tong YS, et al. Reliability and validity of the Chinese version of Beck Suicide Ideation Scale (BSI-CV) in adult community residents. *Chinese Mental Health Journal* 2010;24(4):250-55.
76. Sheehan DV, Lecrubier Y, Sheehan KH, et al. The Mini-International Neuropsychiatric Interview (MINI): the development and validation of a structured diagnostic psychiatric interview for DSM-IV and ICD-10. *The Journal of Clinical Psychiatry* 1998;58(Suppl 20):22–33.
77. Si T, Shu L, Dang W, et al. Evaluation of the Reliability and Validity of Chinese Version of the Mini.International Neuropsychiatric Interview in Patients with Mental Disorders. *Chinese Mental Health Journal* 2009;23(7):493-97,503.
78. Lecrubier Y, Sheehan DV, Weiller E, et al. The Mini International Neuropsychiatric Interview (MINI). A short diagnostic structured interview: reliability and validity according to the CIDI. *European Psychiatry* 1997;12(5):224-31.
79. Fan X, Wei J, Zhang J. On Reliability and validity of Social Connectedness Scale-Revised in Chinese middle school students. *Journal of Southwest China Normal University (Natural Science Edition)* 2015;40(8):118-22.
80. Lee RM, Robbins SB. Measuring belongingness: the social connectedness and the social assurance scales. *Journal of Counseling Psychology* 1995;42(2):232.
81. Koenig HG, Westlund RE, George LK, et al. Abbreviating the Duke Social Support Index for use in chronically ill elderly individuals. *Psychosomatics* 1993;34(1):61-9. doi: 10.1016/s0033-3182(93)71928-3
82. Zhou M, Qiu J, Mou Y, et al. Reliability and validity of the 23-Duke Social Support Scale among rural elderly population. *Chinese Journal of Public Health* 2015;31(11):1369-72.
83. Hou F, Cerulli C, Wittink M, et al. Depression, social support and associated factors among women living in rural China: a cross-sectional study. *BMC Women's health* 2015;15(1):28.
84. Zhang J, Conwell Y, Wieczorek WF, et al. Studying Chinese suicide with proxy-based data: reliability and validity of the methodology and instruments in China. *Journal of Nervous and Mental Disease* 2003;191(7):450.
85. Jia C, Zhang J. Psychometric characteristics of the Duke Social Support Index in a young rural Chinese population. *Death Studies* 2012;36(9):858-69.
86. Link BG, Struening EL, Neese-todd S, et al. On describing and seeking to change the experience of stigma. *Psychiatric Rehabilitation Skills* 2002;6(2):201-31. doi: 10.1080/10973430208408433
87. Xu H. A study of stigma of people with Schizophrenia and relationship with medication compliance. Peking Union Medical College, 2008.
88. Zhang JX, Schwarzer R. Measuring optimistic self-beliefs: A Chinese adaptation of the General Self-Efficacy Scale. *Psychologia: An International Journal of Psychology in the Orient* 1995;38(3):174–181.

89. Liamputtong P. Researching the vulnerable: A guide to sensitive research methods: Sage 2006.
90. Liamputtong P. Qualittive Research Methods. Fourth ed. Australia: Oxford University Press 2013:218-237.
91. Inagaki M, Kawashima Y, Kawanishi C, et al. Interventions to prevent repeat suicidal behavior in patients admitted to an emergency department for a suicide attempt: a meta-analysis. *Journal of Affective Disorder*s 2015;175:66-78.
92. Mann JJ, Apter A, Bertolote J, et al. Suicide prevention strategies: a systematic review. *JAMA* 2005;294(16):2064-74.
93. World Health Organization. Global Health Observatory data repository 2019. Available from http://apps.who.int/gho/data/?theme=main. Assessed at October 23rd 2019.
94. Zhao W, Zhu Y, Luo XW, et al. The assertive community treatment model for severe mental disorders: A review. Chinese Mental Health Journal 2014;28(2):89-96.
95. Shenzhen Mental Health Center. Shenzhen Mental Health Work Information Brief Shenzhen: Shenzhen Mental Health Center, 2020.
96. Schechter M, Goldblatt MJ, Ronningstam E, et al. Postdischarge suicide: a psychodynamic understanding of subjective experience and its importance in suicide prevention. *Bulletin of the Menninger Clinic* 2016;80(1):80-96.

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Contributors All authors contributed to the conceptualization and the design of this study. FH obtained the funding and contributed to the theoretical framework of the study. FH and HL conceived the prototype of the intervention, the study design, and the creation of the team. HL and GC drafted the initial manuscript together. JL and CH provided the sampling, randomization, and analytical strategy. BZ and YB conceived the content of the intervention and provided crisis intervention service in the study. LS, CC and HX contributed to the implementation of the study. TL and EDC steered the direction of the study and contributed significantly to the revision

of the manuscript. All authors read and revised the initial manuscript and approved the final version.

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Competing interests All authors declare no competing interest.

Ethics approval Ethics Committee Review Board of Shenzhen Kangning Hospital (2021-K006-01-1).

Data sharing statement We will make quantitative data publicly available through FigShare 12 months after the main studies are published in peer-reviewed journals. The data will contain unidentified demographic information, primary and secondary outcomes, and other covariate outcomes. Please contact the PI to request for the use of the data, and the requests should include detail contact information of applicants, the purpose of study, and the analysis plan.

Table 1 The definition of suicide behaviors in this study

Suicide behaviors	Definition
Suicidal ideation	Having a clear intent to harm oneself without a clear plan, nor taking any preparation or actions.
Suicidal plan	Having a clear plan to harm oneself without taking any preparation or actions.
Suicidal preparation	Taking any preparation to commit suicide without taking actions to harm oneself.
Attempted suicide	Taking actions to commit suicide with a certain intensity of wish to die, which did not directly result in a fatal outcome.
Completed suicide	Taking actions to commit suicide with a certain wish to die and directly resulting in death

Figure caption:

Figure 1 The Implementation Outcomes Framework

Figure 2 The summary of the study design

Figure 3 The SMART design trial

Figure 4 An example of the brief contact intervention delivered through WeChat

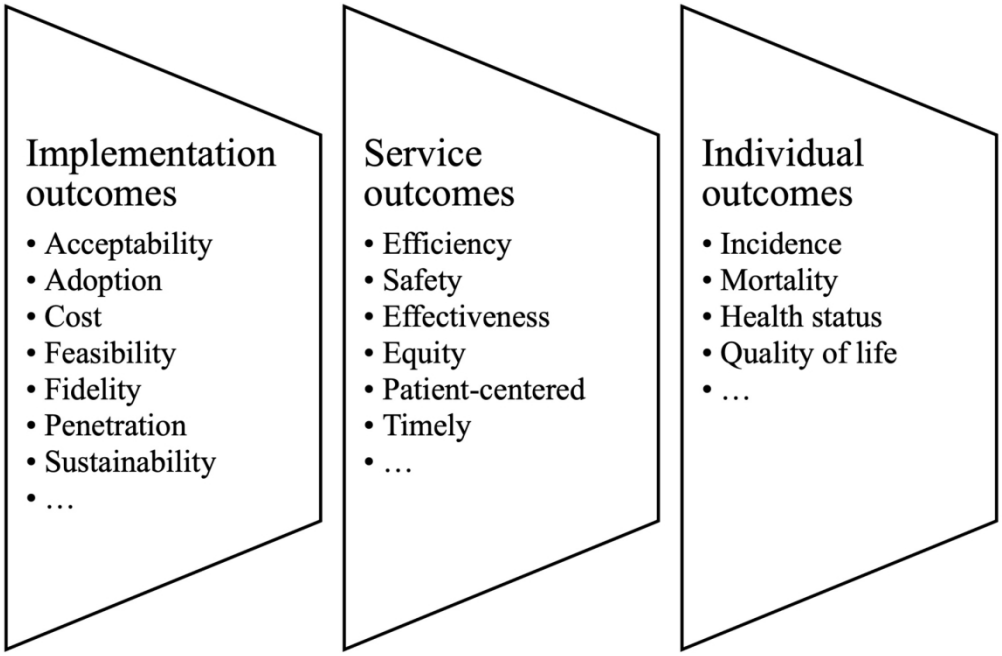

Figure 1 The Implementation Outcomes Framework

169x110mm (300 x 300 DPI)

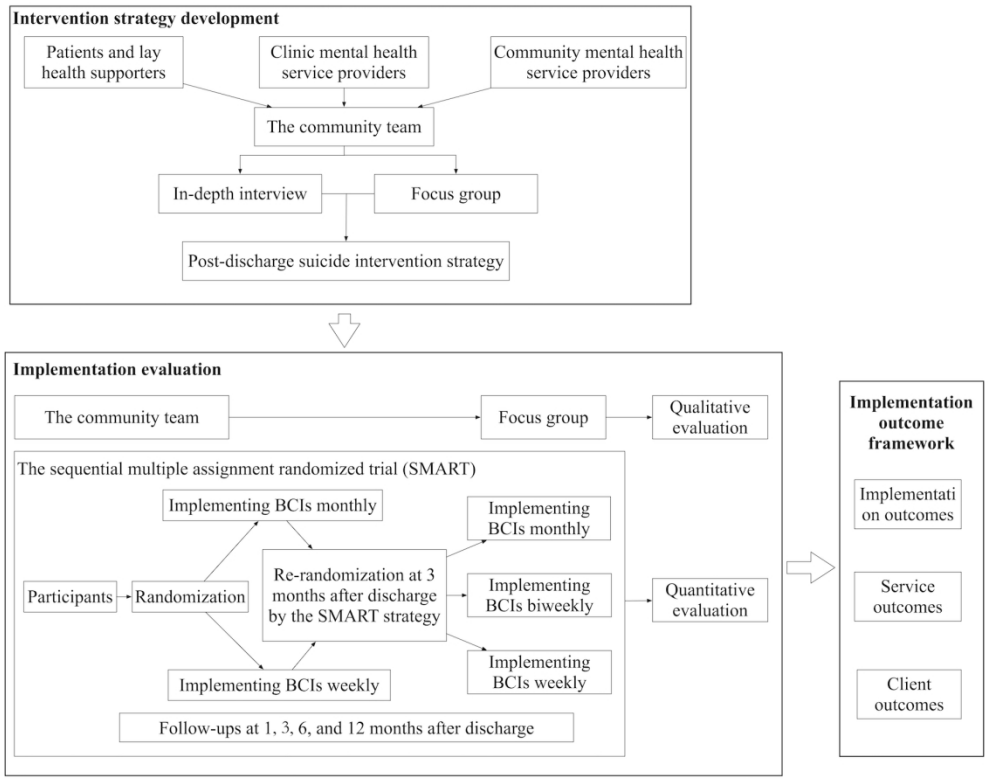

Figure 2 Summary of the study design

162x127mm (300 x 300 DPI)

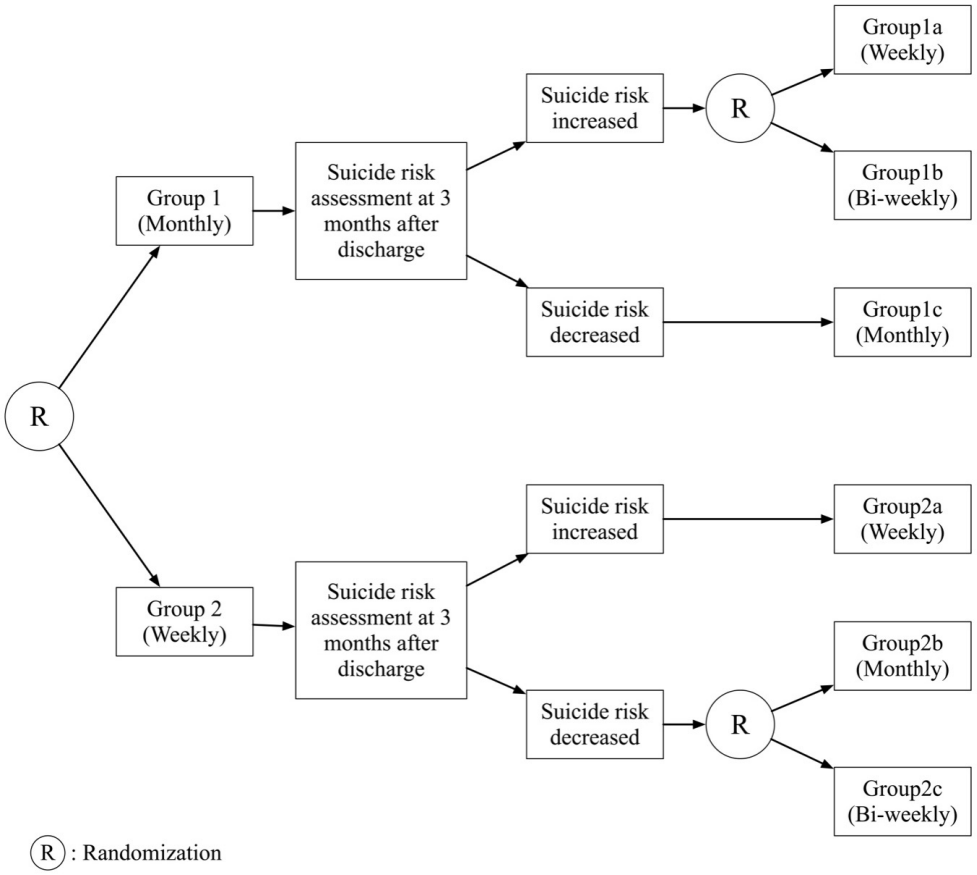

Figure 3 The SMART design trial

159x141mm (220 x 220 DPI)

Figure 4 An example of the brief contact intervention delivered through WeChat

368x330mm (300 x 300 DPI)

Informed Consent for the Sequential Multiple Assignment Trial

Dear Sir/Madam,

We invite you to take part in this study. Before you decide whether to participate in, you need to know why we are doing this study and what to look for. If you are unsure about anything or want to know more about the study, please ask questions while the research assistant is discussing this informed consent with you. If you have questions now or during the study, the research assistant will answer them for you. You will have plenty of time to consider the advice and recommendations from your family and friends before you make the decision.

If you are taking part in any other studies, please inform the research assistant.

PI: Fengsu Hou.

Sponsor: Shenzhen Kangning Hospital /Shenzhen Mental Health Center

Founding: Natural Science Foundation of China

Part 1 Introduction

1. Abstract

The post-discharge suicide risk of psychiatric patients is significantly higher than it is among general population and patients with other diseases. Currently, there lacks interventions for post-discharge suicide in China. The World Health Organization recommends the low-cost brief contact interventions (BCIs) for reducing the risk in areas with limited resource of mental health service. To embed BCIs into routine work in community mental health service, it is critical to determine the best frequency to contact patients and the effects of implementation. Based on BCIs, this study aims to develop an interventional strategy against post-discharge suicide for Chinese psychiatric patients; then, based on the Implementation Outcome Framework and Sequential Multiple Assignment Randomized Trial, this study also aims to determine the best frequency of

BCIs, to evaluate the implementation process and outcomes of the strategy, and the possibility and sustainability of routine implementation. Finally, the findings will provide evidence for developing innovative management against post-discharge suicide for psychiatric patients and pioneer the application of implementation science in mental health.

2. Participants

The study will recruit patients with psychotic symptoms and patients with major depressive disorder (MDD) discharged from Shenzhen Kangning Hospital, as in representative of severe and non-severe mental disorders, separately.

3. Procedure of the study

If you agreed to participate in this study, please sign at the end of this consent form. Then the research assistant will conduct a survey to collect data as following topics:

- Sociodemographic information
- Physical and mental health
- Utilization of health services and compliance to treatment
- Social connectedness and social support
- Perceived stigma and self-efficacy
- Suicide risk

Once you have finished the survey, the research assistant will help you subscribe to the study's WeChat Mini Program or help you download and log in to the application on your smartphone. If you don't use a smartphone or prefer text messages and phone calls, please tell the research assistant.

After discharge, you will receive brief contact messages through WeChat, the application, text messages, or phone calls.

At 1-, 3-, 6- and 12-month after your discharge, there will be follow-up surveys.

4. Potential risk and coping strategy

A possible risk in this study is the leakage of personal information, including sociodemographic information, psychiatric diagnosis, and suicide risk.

This study affirms that patients' refusal to participate in the study during the informed consent process or withdrawal during the study will not affect the quality of medical services received from Shenzhen Kangning Hospital/ Shenzhen Mental Health Center, and

the study team will ensure that patients' rights will not be violated.

All data is stored in encrypted form and backed up on a storage device not connected to the Internet. Only the principal investigator and specific analysts have access to view, manage, and analyze the data.

During analysis, all processes will be only performed on the computer dedicated to this study. Copying or dissemination data in any format and method is strictly prohibited.

There will be follow-up surveys at 1, 3, 6 and 12 months after discharge. If the survey results indicate you relapsed or were at risk of suicide, we will intervene and help you as following ways:

- The research team will cooperate with the crisis intervention team from Shenzhen Kangning Hospital. We will try to contact you, initiate psychological crisis intervention, encourage you to visit out-patient clinic, and assist in treatment as needed.
- The research team will contact your family to inform them of your suicide risk, encourage them to accompany you to visit out-patient clinic, and advise on home care and precautions for managing suicide risk.
- If you relapsed, the research team will cooperate with the clinical staff of Shenzhen Kangning Hospital to contact you, explain your current symptoms, encourage you to take medicine as prescribed and to visit out-patient clinic timely.

Lastly, if you are found to be at risk of violent behaviors towards the public, the research team will collaborate with the Shenzhen Kangning Hospital to contact your family members to inform them of the risk, notify the community mental health workers in your community to conduct face-to-face visits, and assist in treatment as needed, in accordance with the requirements of the Code of Practice for the Management and Treatment of Severe Mental Disorders (2018 version).

5. Benefits

Participation in this study does not affect the quality of clinical care you receive. However, through this study, you can understand your current mental health status and receive reminders for follow-up visits, which beneficial for early prevention, diagnosis, and intervention.

6. Cost

You don't need to pay any fees to join the study.

7. Compensation

By taking part in this study, we will pay you RMB 100 Yuan as compensation for the cost of your time.

8. Participation principle

Your participation in this study is voluntary. You may opt out at any time during the study. There will be no prejudice and your benefits will not be compromised.

Refusal or withdrawal from the survey will not affect your future access to clinical care or the quality of the services involved.

9. Privacy

Your personal information is confidential and will be unidentified, encrypted, and stored. All data collected in this study are only for the research purposes and there is no commercial or other use. The results of this study may be published in academic journals/books, but your name or any other information that identifies you will not appear in any published materials. Subject-identifiable information will not be disclosed to members outside the research team unless your permission is obtained. Only the principal investigator and specific analysts have access to view, manage, and analyze the data. To ensure that the research is conducted in accordance with the regulations, members of the government administration or ethics review committee will have access to your personal information as required.

10. Contact information

If you have any questions related to this study, please contact the principal investigator: Fengsu Hou，18502864780.

If there are any questions about your rights/interests, or if you want to report the difficulties, dissatisfaction or concerns encountered about participating in this study, or if you want to provide comments and suggestions related to this study, please contact the Ethics Committee Office of Shenzhen Kangning Hospital. Telephone number 0755-

82926524. Email: kangning_ethics@163.com.

Part 2 Informed Consent and Signature

Consent declaration:

I have fully discussed and understood the background, purposes, and procedures of this study. I have been given plenty of time and opportunity to ask questions, and the answers to my questions are satisfactory. I was also told who to contact when I had questions or wanted further information. I have read this informed consent form and I agree to participate in this study. I understand that I can withdraw from this study at any point without any reason.

I agree to participate in this study and I will complete the study with the assistance of research assistants.

Signature：

Date：

Informed Consent for Qualitative Interviews

Dear Sir/Madam,

We invite you to take part in this study. Before you decide whether to participate in, you need to know why we are doing this study and what to look for. If you are unsure about anything or want to know more about the study, please ask questions while the research assistant is discussing this informed consent with you. If you have questions now or during the study, the research assistant will answer them for you. You will have plenty of time to consider the advice and recommendations from your family and friends before you make the decision.

If you are taking part in any other studies, please inform the research assistant.

PI: Fengsu Hou.

Sponsor: Shenzhen Kangning Hospital /Shenzhen Mental Health Center

Founding: Natural Science Foundation of China

Part 1 Introduction

1. Abstract

The post-discharge suicide risk of psychiatric patients is significantly higher than it among general population and patients with other diseases. Currently, there lacks interventions for post-discharge suicide in China. The World Health Organization recommends the low-cost brief contact interventions (BCIs) for reducing the risk in areas with limited resource of mental health service. To embed BCIs into routine work in community mental health service, it is critical to determine the best frequency to contact patients and the effects of implementation. Based on BCIs, this study aims to develop an interventional strategy against post-discharge suicide for Chinese psychiatric patients; then, based on the Implementation Outcome Framework and Sequential Multiple Assignment Randomized Trial, this study also aims to determine the best frequency of BCIs, to evaluate the implementation process and outcomes of the strategy, and the

possibility and sustainability of routine implementation. Finally, the findings will provide evidence for developing innovative management against post-discharge suicide for psychiatric patients and pioneer the application of implementation science in mental health.

2. Participants

The study will recruit patients with psychotic symptoms and patients with major depressive disorder (MDD) discharged from Shenzhen Kangning Hospital, their lay health supporters, psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers.

3. Procedure of the study

If you agreed to participate in this study, please sign at the end of this consent form. Then the research assistant will conduct a survey about your sociodemographic information and then conduct the interview to explore your opinions about following topics:

For patients and lay health providers

- Previous experience of discharge from psychiatric facilities
- Expectations and needs for post-discharge suicide risk management
- Social connectedness and social support
- Attitudes towards brief contact intervention
- Evaluations related to the implementation of brief contact intervention

For psychiatrists and nurses, psycho-crisis intervention team members, community mental health workers and mental health social workers

- Experience related to suicide risk management
- Suggestions and expectations for suicide risk management of patients with mental disorder
- Patients' social connectedness and social support
- Attitudes towards brief contact intervention
- Evaluations related to the implementation of brief contact intervention

Interviews will be recorded for analysis.

4. Potential risk and coping strategy

A possible risk in this study is the leakage of personal information, including

sociodemographic information, psychiatric diagnosis, and suicide risk.

This study affirms that patients' refusal to participate in the study during the informed consent process or withdrawal during the study will not affect the quality of medical services received from Shenzhen Kangning Hospital/ Shenzhen Mental Health Center, and the study team will ensure that patients' rights will not be violated.

All data is stored in encrypted form and backed up on a storage device not connected to the Internet. Only the principal investigator and specific analysts have access to view, manage, and analyze the data.

During analysis, all processes will be only performed on the computer dedicated to this study. Copying or dissemination data in any format and method is strictly prohibited.

5. Benefits

Participation in this study does not affect the quality of clinical care you receive. However, through this study, you can understand your current mental health status and receive reminders for follow-up visits, which are beneficial for early prevention, diagnosis, and intervention.

6. Cost

You don’t need to pay any fees to join the study.

7. Compensation

By taking part in this study, we will pay you RMB 100 Yuan as compensation for the cost of your time.

8. Participation principle

Your participation in this study is voluntary. You may opt out at any time during the study. There will be no prejudice and your benefits will not be compromised.

Refusal or withdrawal from the interview will not affect your future access to clinical care or the quality of the services involved.

9. Privacy

Your personal information is confidential and will be unidentified, encrypted, and stored. All data collected in this study are only for the research purposes and there is no

commercial or other use. The results of this study may be published in academic journals/books, but your name or any other information that identifies you will not appear in any published materials. Subject-identifiable information will not be disclosed to members outside the research team unless your permission is obtained. Only the principal investigator and specific analysts have access to view, manage, and analyze the data. To ensure that the research is conducted in accordance with the regulations, members of the government administration or ethics review committee will have access to your personal information as required.

10. Contact information

If you have any questions related to this study, please contact the principal investigator: Fengsu Hou , 18502864780.

If there are any questions about your rights/interests, or if you want to report the difficulties, dissatisfaction or concerns encountered about participating in this study, or if you want to provide comments and suggestions related to this study, please contact the Ethics Committee Office of Shenzhen Kangning Hospital. Telephone number 0755-82926524. Email: kangning_ethics@163.com.

Part 2 Informed Consent and Signature

Consent declaration:

I have fully discussed and understood the background, purposes, and procedures of this study. I have been given plenty of time and opportunity to ask questions, and the answers to my questions are satisfactory. I was also told who to contact when I had questions or wanted further information. I have read this informed consent form and I agree to participate in this study. I understand that I can withdraw from this study at any point without any reason.

I agree to participate in this study and I will complete the study with the assistance of research assistants.

Signature：

Date：

Interview Guide Questions for Intervention Development
(For patients)

1. What is the biggest problem you might face after discharge?

2. From your opinion, what might cause relapses after discharge?

3. From your opinion, what might increase suicide risk after discharge?

4. For the problems mentioned, what kind of help do you need?

5. How would you like clinical and community mental health providers to help? Please explain your expectations as well.

6. We are considering implementing follow-ups to reduce suicide risk after discharge, and what kind of follow-up services do you prefer?

7. Brief contact interventions (BCIs) are a series of low cost and non-intrusive interventions to maintain long-term contact with patients, and we plan to use BCIs to deliver the follow-ups patients and their lay health supporters. What content do you prefer or expect from the contacts?

8. What's the appropriate frequency to contact you?

9. Will the BCIs make you more willing to pay regular visits to out-patient clinics? Please explain to us.

10. In general, what is the most important to reduce suicide risk after discharge?

11. Do you feel less connected to others during hospitalization?

12. If you have been hospitalized before, have you experienced any loss of social connectedness after discharge?

13. Are you worried about having less connectedness after discharge now?

14. Under what circumstances would you feel more connected to others?

15. Do you receive any help and support during hospitalization? What are they?

16. If you have been hospitalized before, have you experienced any loss of support after discharge?

17. Are you worried about having less support after discharge now?

18. Under what circumstances would you feel more supported?

In-depth/Focus Group Interview Guide Questions for Intervention Development (Lay health supporters)

1. What is the biggest problem the patient might face after discharge?

2. From your opinion, what might cause their relapses after discharge?

3. From your opinion, what might increase their suicide risk after discharge?

4. For the problems mentioned, what kind of help do you and/or the patient need?

5. How would you like clinical and community mental health providers to help you and the patient? Please explain your expectations as well.

6. We are considering implementing follow-ups to reduce suicide risk after discharge, and what kind of follow-up services do you prefer?

7. Brief contact interventions (BCIs) are a series of low cost and non-intrusive interventions to maintain long-term contact with patients, and we plan to use BCIs to deliver the follow-ups to patients and their lay health supporters. What content do you prefer or expect from the contacts?

8. What's the appropriate frequency to contact you or the patient?

9. Will the BCIs make the patient more willing to pay regular visits to out-patient clinics? Please explain to us.

10. In general, what is the most important to reduce suicide risk after discharge?

11. Do you feel the patient is less connected to others during hospitalization?

12. If the patient has been hospitalized before, did he or she experience any loss of social connectedness after discharge?

13. Are you worried about the patient having less connectedness after discharge?

14. Under what circumstances would the patient feel more connected to others?

15. Does the patient receive help and support during hospitalization?

16. If the patient has been hospitalized before, did he or she experience any loss of support after discharge?

17. Are you worried about the patient having less support after discharge?

18. Under what circumstances would the patient feel more supported?

In-depth/Focus Group Interview Guide Questions for Intervention Development (Clinic and community mental health service providers)

1. Is there a need for suicide risk management in mental health services?

2. Is it necessary to focus on reducing suicide risk among psychiatric patients after discharge? Please explain to us.

3. How would you implement post-discharge suicide risk management from your perspective?

4. Please briefly introduce your experience in patient suicide risk management.

5. Have there been any incidents of suicides or threats of suicide by patients? If yes, how did you handle it and what do you learn from it? If no, how would you handle it?

6. In general, what is the most pressing need to reduce suicide risk after discharge?

7. We are considering implementing follow-ups to reduce suicide risk after discharge, and what kind of follow-up services will you suggest?

8. Brief contact interventions (BCIs) are a series of low cost and non-intrusive interventions to maintain long-term contact with patients, and we plan to use BCIs to deliver the follow-ups to patients and their lay health supporters. What content would you like to deliver?

9. What's the appropriate frequency to contact patients?

10. Will the BCIs make patients more willing to pay regular visits to out-patient clinics? Please explain to us.

11. How to improve social connectedness and social support for patients through such intervention?

12. How to increase patients' follow-up visits to out-patient clinic, increase compliance and acceptance of follow-ups through such intervention?

13. What would patients' and lay health supporters' attitudes be towards the acceptance and adoption of the suicide risk intervention? Please explain to us.

14. How to be patient-centered in such intervention?

15. Is there any potential risk to patients when implementing the BCIs?

In-depth/Focus Group Interview Guide Questions for Intervention Evaluation (Patients and lay health supporters)

1. What's your attitude toward the acceptability of implementing brief contact interventions (BCIs) to reduce post-discharge suicide risk? Please explain to us.

2. Do you think BCIs are feasible in daily lives? Please explain to us.

3. After discharge, will you adopt BCIs to reduce suicide risk? Please explain to us.

4. Do you think BCIs pose potential risk or harm to the patients?

5. What do you think about the equity of BCIs? Please explain to us.

6. As we have introduced BCIs, including the content, the way to implement and the frequency to contact patients, do you think BCIs are patient-centered and fully taking account of your needs and feelings? Please explain to us.

7. Do you have any suggestions of implementing BCIs to reduce post-discharge suicide risk among psychiatric patients?

In-depth/Focus Group Interview Guide Questions for Intervention Evaluation (Clinic and community mental health service providers)

1. Do you accept to implement brief contact interventions (BCIs) as a routine service for discharged psychiatric patients?

2. Do you think BCIs are feasible in your daily work? Please explain to us.

3. Will you adopt BCIs to reduce suicide risk after discharge in follow-ups? Please explain your opinions to us.

4. Do you think BCIs pose potential risk or harm to the patients?

5. Would you please share your opinions about how BCIs reduce post-discharge suicide risk among psychiatric patients?

6. What do you think about the equity of BCIs? Please explain to us.

7. As we have introduced BCIs, including the content, the way to implement and the frequency to contact patients, do you think BCIs are patient-centered and fully taking account of your needs and feelings?

8. Will implementing BCIs meet your needs in your work related to suicide risk management?

9. Do you have any suggestions of implementing BCIs to reduce post-discharge suicide risk among psychiatric patients?

COREQ (COnsolidated criteria for REporting Qualitative research) Checklist

A checklist of items that should be included in reports of qualitative research. You must report the page number in your manuscript where you consider each of the items listed in this checklist. If you have not included this information, either revise your manuscript accordingly before submitting or note N/A.

Topic	Item No.	Guide Questions/Description	Reported on Page No.
Domain 1: Research team and reflexivity			
Personal characteristics			
Interviewer/facilitator	1	Which author/s conducted the interview or focus group?	15
Credentials	2	What were the researcher's credentials? E.g. PhD, MD	1
Occupation	3	What was their occupation at the time of the study?	N/A
Gender	4	Was the researcher male or female?	N/A
Experience and training	5	What experience or training did the researcher have?	15
Relationship with participants			
Relationship established	6	Was a relationship established prior to study commencement?	N/A
Participant knowledge of the interviewer	7	What did the participants know about the researcher? e.g. personal goals, reasons for doing the research	N/A
Interviewer characteristics	8	What characteristics were reported about the inter viewer/facilitator? e.g. Bias, assumptions, reasons and interests in the research topic	N/A
Domain 2: Study design			
Theoretical framework			
Methodological orientation and Theory	9	What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis	26
Participant selection			
Sampling	10	How were participants selected? e.g. purposive, convenience, consecutive, snowball	14
Method of approach	11	How were participants approached? e.g. face-to-face, telephone, mail, email	14
Sample size	12	How many participants were in the study?	14,15
Non-participation	13	How many people refused to participate or dropped out? Reasons?	N/A
Setting			
Setting of data collection	14	Where was the data collected? e.g. home, clinic, workplace	15
Presence of non-participants	15	Was anyone else present besides the participants and researchers?	N/A
Description of sample	16	What are the important characteristics of the sample? e.g. demographic data, date	N/A
Data collection			
Interview guide	17	Were questions, prompts, guides provided by the authors? Was it pilot tested?	Supplement file
Repeat interviews	18	Were repeat inter views carried out? If yes, how many?	N/A
Audio/visual recording	19	Did the research use audio or visual recording to collect the data?	15
Field notes	20	Were field notes made during and/or after the inter view or focus group?	15
Duration	21	What was the duration of the inter views or focus group?	N/A
Data saturation	22	Was data saturation discussed?	N/A
Transcripts returned	23	Were transcripts returned to participants for comment and/or	N/A

Topic	Item No.	Guide Questions/Description	Reported on Page No.
		correction?	
Domain 3: analysis and findings			
Data analysis			
Number of data coders	24	How many data coders coded the data?	26
Description of the coding tree	25	Did authors provide a description of the coding tree?	N/A
Derivation of themes	26	Were themes identified in advance or derived from the data?	N/A
Software	27	What software, if applicable, was used to manage the data?	26
Participant checking	28	Did participants provide feedback on the findings?	14
Reporting			
Quotations presented	29	Were participant quotations presented to illustrate the themes/findings? Was each quotation identified? e.g. participant number	N/A
Data and findings consistent	30	Was there consistency between the data presented and the findings?	N/A
Clarity of major themes	31	Were major themes clearly presented in the findings?	N/A
Clarity of minor themes	32	Is there a description of diverse cases or discussion of minor themes?	N/A

Developed from: Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a 32-item checklist for interviews and focus groups. *International Journal for Quality in Health Care*. 2007. Volume 19, Number 6: pp. 349 – 357

Once you have completed this checklist, please save a copy and upload it as part of your submission. DO NOT include this checklist as part of the main manuscript document. It must be uploaded as a separate file.

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	____1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	_4 , 29 , clinicaltrials.gov _____
	2b	All items from the World Health Organization Trial Registration Data Set	__Not applicable_____
Protocol version	3	Date and version identifier	__26_____
Funding	4	Sources and types of financial, material, and other support	__37_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	_1, 2, 36_____
	5b	Name and contact information for the trial sponsor	_2_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	_36_____

	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	_25_____
Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	_6-9_____
	6b	Explanation for choice of comparators	__15,16_____
Objectives	7	Specific objectives or hypotheses	_9_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	_12-16,18_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_11,12_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_14,16,17_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_15,_18_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	_15_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	_19___ _____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	__Not applicable_

Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	_19-23_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	_15,16_____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	_13,17_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_19_____

Methods: Assignment of interventions (for controlled trials)

Allocation:

Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	_18_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	_18_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	_18_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	_18_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	_Not applicable_____

Methods: Data collection, management, and analysis

Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	_19_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	_19_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	_19,25_____
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	_23,24_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	_23,24_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	_25_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	_Not applicable_
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	_Not applicable_
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	_Not applicabl _
Ethics and dissemination			

Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	__26_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	_Not applicable_
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	_25_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	_Not applicable_
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	_37_____
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	_37_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	_25,37_____ _
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	_Not applicable__
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	_26_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	_Not applicable__
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	_37____ ____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	_Not applicable__

Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	_Not applicable__

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.